UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, Plaintiff, vs. ALBERT POET, Defendant.	: Anne E. Thompson, U.S.D.J. Criminal Number 06- 18 U.S.C. § § 1341 and 2; 21 U.S.C. § § 331(k); 333(a)(2); and 352(i)(3)

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT'S PRETRIAL MOTIONS

William J. Hughes, Jr., Esq.
COOPER LEVENSON APRIL NIEDELMAN & WAGENHEIM, P.A.
1125 Atlantic Avenue, 3rd Floor
Atlantic City, NJ 08401
609-344-3161
Attorneys for Defendant, Albert Poet

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PRELIMINARY STATEMENT

By even the most objective standards, the Government's case against the doctor appears to conclusively prove his guilt. From the investigative reports alone, the doctor apparently convinced his clients that the mixture of Botulinum Neurotoxin Type A (hereinafter BoNT/A) he offered was a safe, legal and effective alternative to Allergan's BOTOX® Cosmetic product. Indeed, one patron was told that the alternative BoNT/A "was legal to use and that other doctors were using it in place of Botox." Hughes Cert., at ¶ 2, Exhibit 1. Another customer was told that the alternative BoNT/A was "awaiting FDA approval" and that "it could be used on humans." Id. at ¶ 3, Exhibit 2. Yet another client recalls how the doctor told him how the product was "the same as Botox® Cosmetic" and how the doctor's literature "always 'talked about the safety'" of the product. Id. at ¶ 4, Exhibit 3.

The doctor told his customers these things despite the fact that the alternative BoNT/A he offered had the words "FOR RESEARCH PURPOSES ONLY – NOT FOR HUMAN USE" printed on the side of the vial. Not surprising, the doctor had an explanation for this too, and the prosecution's reports contain page after page of detail concerning his deception. The doctor told one patron that the warnings were there to "by-pass the patent that Allergan had on their Botox® product" but that the alternative BoNT/A was just "like Allergan's Botox®." Id. at ¶ 5, Exhibit 4. Another customer, who was concerned, was assured that – notwithstanding the warnings – the alternative BoNT/A was "safe to use on humans" and that "it was labeled that way because of trademark issues. . . ." Id. at ¶ 6, Exhibit 5. Indeed, whenever any of the good doctor's clients raised any doubt or concern about the warnings, the prosecution's numerous reports show that the doctor's explanation was nearly always the same: the product the doctor offered was "generic

botox," id. at ¶ 4, Exhibit 3, "no different than Allergan's product," and that the warnings were only "for legal purposes to protect ourselves." Id. at ¶ 7, Exhibit 6.

The Government's reports show that the product the doctor offered was basically identical to Allergan's BOTOX® Cosmetic product. Id. at ¶ 8, Exhibit 7. The prosecution's reports, however, conclusively and completely prove that nearly everything else the doctor told his clients were beyond puffery and exaggeration, they were bold-faced lies designed to deceive and to defraud his customers. The product the doctor offered was never in the FDA approval process, it was not legal for the doctor to offer it to his customers, and the warnings were not placed solely for "legal purposes" or to avoid "trademark issues." Yet the Government's reports, page after page, show that the doctor's clients bought into his deception, and they used his product. For this reason, the Government sought to stop the doctor from continuing to commit his deceptive practices, and quite rightfully so. In the Government's own words, the "United States also seeks to protect individuals from defendants' false and misleading promotion, advertising, education, and treatment, representing and using Botulinum Toxin Type A as an FDA approved drug for human use." Id. at ¶ 9, Exhibit 8 (at page 23, ¶ 40).

Unfortunately for the Government in this case the doctor referred to above is Dr. Chad Livdahl, who the Government already prosecuted and is in jail for fraud and who sold the alternative BoNT/A to Dr. Albert Poet – the defendant in this case – and to over two hundred other physicians and surgeons. The "individuals," *i.e.*, the victims, the Government sought to protect from Livdahl's false, misleading and misbranded promotions were the thousands of physicians and surgeons who, like Dr. Albert Poet, received Livdahl's advertisements.

Based largely upon the evidence outlined above, the Government prevailed and obtained its restraining order against Livdahl and his company, Toxin Research International ("TRI"). It

also secured Livdahl's conviction. ***Now, however, the Government seeks to prosecute one of the same individuals – a fraud victim -- it previously sought to protect, Dr. Albert Poet***. In so doing, however, agents of the Government have ignored federal statutory law mandating a hearing, failed to produce exculpatory evidence and statements of the accused, intimidated and lied to witnesses necessary to the defense, and quite possibly, failed to meet their duties to the grand jury. For the reasons set forth below, Dr. Albert Poet respectfully, and earnestly, urges this Court to dismiss the Indictment. In the alternative, Dr. Poet requests that the Court grant leave to engage in further pretrial discovery necessary to the defense and not otherwise available under Fed. R. Crim. P. 16.

FACTUAL BACKGROUND

Given the complexity of the issues involved in this case, as well as the circumstances underlying the Defense's motions, it is necessary to provide the Court with an extensive background on the substance and the trademark at issue, its history of approval before the FDA, the other prosecutions which led to the instant case, and the investigation and prosecution of the instant case.

A. Botulinum Neurotoxin Type A

1. Overview of the Substance and Botulism

Botulinum Neurotoxin Type A (also called Botulism Toxin Type A) is one of seven protein derivatives of the bacterial organism *Clostridium Botulinum* ("C. Botulinum). Id. at ¶ 10, Exhibit 9 (Center for Disease Controls Botulism Handbook, at page 5). Each of the seven types is designated by sequential alphabetic letters, *i.e.*, Types A through G. Id. Types A, B, E, and in rare cases, F have been known to cause the four types of botulism, the disease, in humans. Id. The protein, once introduced to the body in sufficient quantity, begins to bind at the nerve

endings where the nerves join the muscles. Id. at ¶ 11, Exhibit 10 (FDA Consumer Magazine (Dec. 1995)). The result is an increasing weakness and paralysis that descends from the head down, affecting, among other things, breathing. Id. According to the FDA and the CDC, successful treatment of botulism depends upon the rapid administration of an antitoxin to prevent further *C. Botulinum Toxin* from attaching to nerve endings and the close monitoring of the patient's respiratory functions to determine whether a ventilator is required. Id. at ¶ 10, Exhibit 9 (CDC Manual, at page 13-14).

The disease can be lethal, and indeed, the mortality rate between 1899 and 1950 was approximately 60%. Id. at ¶10, Exhibit 9 (CDC Manual, at page 7). Due to advances in the wide distribution and rapid introduction of the antitoxin, the mortality rate had dramatically decreased by the 1990's to somewhere between 2% (according to the FDA) and 15% (according to the CDC). Id. at ¶ 11, Exhibit 10 (FDA Consumer Magazine); Id. at ¶ 10, Exhibit 9 (CDC Manual, at page 7). It is important to note, however, that there is no dispute as to the incubation period and the onset of symptoms: ***infected individuals begin to display the initial symptoms of the disease (blurred vision, nausea, vomiting, dry mouth) within 18 to 36 hours, but these symptoms can occur as little as six hours or as long as ten days after infection***. Id. at ¶ 10, Exhibit 9 (CDC Manual, at page 11).

2. Botulinum Neurotoxin Type A's Use in Humans and the Genesis of "Botox"

In the early 1960's, an ophthalmologist in California began to study the effect of greatly diluted doses of the botulism toxin on muscle spasms in the optic nerve. Id. at ¶ 12, Exhibit 11 (FDA Medical Officer Review, at page 12). By the late 1970s, Botulinum Neurotoxin Type A was being used in clinical trials for the treatment of strabismus, otherwise known as "cross-eye" and "lazy-eye." Id. In this regard, the California ophthalmologist who first began the studies,

Dr. Alan Scott, cultivated a strain of BoNT/A and utilized it in his research under a name he trademarked in 1981, "Oculinum." Id. at ¶ 13, Exhibit 12. Dr. Scott's company, Oculinum, Inc. obtained FDA "Orphan Drug" approval to begin testing Oculinum's effectiveness on humans for various eye ailments in 1984. Researchers soon discovered, however, that this was not the only use for BoNT/A. Indeed, by at least 1986, researchers had discovered that BoNT/A could be used on a wide variety of dystonias, *i.e.*, neurological movement disorders characterized by involuntary muscle contractions, which force certain parts of the body into abnormal, sometimes painful, movements or postures. Oculinum, Inc. received approval to expand its testing use in 1986 to various "dystonias." Most interesting, however, is that ***beginning in the mid-1980s to the early 1990s, physicians and researchers began to commonly refer to Botulinum Toxin Type A in academic journals as BOTOX***.

In November 1986, five researchers explained their results from using BoNT/A on "spastic dysphonia" and "other cranial dystonias," including those of the larynx (throat), in a letter to an academic journal dedicated to Ear Nose and Throat Physicians. Id. at ¶ 14, Exhibit 13. In this letter, the researchers explained, "We would like to share our experience using botulinum toxin (BOTOX) for the treatment of 'spastic dysphonia' as part of a trial of toxin injections for the treatment of other cranial dystonias." Id. Throughout the remainder of the letter, the research physicians continually referred to BOTOX as a generic contraction for Botulinum Toxin. Id.

Between 1986 and November 1991, ***foreign and domestic*** physicians, researchers, medical groups, and even the news media used the terms Botox, BOTOX, or BoTox, as generic contractions for Botulinum Toxin. Id. at ¶¶ 14-31, Exhibits 13 through 30. Our limited research has revealed *at least* 15 academic articles, 2 news articles, and 1 medical academy policy

statement utilizing these terms during this time frame. Id. The import of this widespread use of the term Botox has significant repercussions on the Government's ability to pursue this case as a matter of law.

On December 29, 1989, the FDA gave final approval for the use of Dr. Alan Scott's Oculinum as an Orphan Drug under 21 U.S.C. § 360aa, et seq. Id. at ¶ 12, Exhibit 11 (FDA Medical Officer's Review, at page 5). It should be noted that Allergan, Inc. obtained the rights to market and to use Oculinum in research projects from Occulinum, Inc. in 1988. After Oculinum was approved for market in 1989, Allergan marketed the product under Dr. Scott's trademarked name, "Oculinum." Id. at ¶ 24, Exhibit 23. Eventually, FDA approved the use of BoNT/A for various cervical dystonias (1991) and, as most commonly known, to reduce certain forehead wrinkles (2002). Id. at ¶ 32, Exhibit 31 (FDA Warning Letter to Allergan (June 23, 2003)).

Today, the FDA admits that there is widespread off-label (unauthorized ***but legal***) use of BoNT/A to treat a wide variety of maladies and conditions. Id. at ¶ 12, Exhibit 11 (FDA Medical Officer's Review, at pages 16-24). From alleviating the conditions of those stricken with cerebral palsy, strokes, migraine headaches and various dystonias to treating excessive sweating and overactive bladders, BoNT/A has become a common and accepted substance in the practice of medicine. Certainly, as with any other medication, the danger associated with Botulinum Toxin remains, but even the FDA has been impressed by its safety record as a treatment for various human conditions. As acknowledged by Bill Habig, Ph.D, the FDA's former director of biology products, Botulinum Toxin has "an amazing safety record." Id. at ¶ 11, Exhibit 10 (FDA Consumer Magazine). Despite the FDA's initial concern, Habig has stated that the toxin, as a therapeutic substance, "has turned out to be very safe." Indeed, there have

been no reported cases of botulism fatalities resulting from the use of BoNT/A in humans since 1985, and four confirmed cases of botulism resulting from its overdose. Those four cases are discussed below, as it is apparent that Government agents have misrepresented the incident causing these infections to certain of the defense's witnesses in this litigation.

B. Allergan, Inc. and it's Invalid Trademark on BOTOX

The FDA and Allergan, Inc. would have the world believe that Botox was the name Allergan, Inc. created to describe its proprietary BoNT/A, but that just isn't so. In fact, Government records reveal that Allergan, Inc. submitted an untrue statement[1] to the U.S. Patent and Trademark Office in its initial application by wrongly indicating the date of its first use in the public domain.

On about June 28, 1991, about a year and a half after the FDA approved Oculinum for use in certain eye disorders, Allergan, Inc. purchased Oculinum, Inc. and all of its intellectual property, including the trademark for Oculinum. Id. at ¶ 33, Exhibit 32. On February 2, 1991, Allergan, Inc. filed an application to register the name BOTOX for "Pharmaceutical preparations for the treatment of neurologic disorders, in class 5." Id. at ¶ 34, Exhibit 33. This trademark was accepted by the U.S. PTO on August 18, 1992. Id. On December 21, 1990, Allergan, Inc. filed a second application to register the name BOTOX for "Pharmaceutical preparations: namely, ophthalmic muscle relaxants, in class 5." Id. at ¶ 35, Exhibit 34. This trademark was accepted by the U.S. PTO on June 9, 1992. Id.

In both trademark applications, Allergan, Inc. submitted a "Declaration of First Use" to the PTO, under the penalty of perjury, stating that ***the first use of BOTOX was in September, 1990*** and that its first use in commerce was on January 22, 1992. Id. at ¶¶ 34-35, Exhibits 33

[1] If this were a civil action to invalidate Allergan's BOTOX trademark, the cause of action would be fraud upon the U.S. PTO.

and 34. The problem is that Allergan, Inc.'s sworn statement that the first use of the term BOTOX was in September 1990 simply was not true. Since at least 1986, five years prior to Allergan, Inc.'s first application to the U.S. PTO, physicians, researchers, medical societies, and even the news media used the term Botox as a generic description and contraction for Botulinum Neurotoxin. Id. at ¶¶ 14–31, Exhibits 13–30. ***To intellectual property lawyers, the import of these facts is obvious: generic names cannot, under any circumstances, be trademarked, and knowing failure to advise the U.S. PTO of a trade-name's true prior use constitutes fraud resulting in the invalidation of the mark as a matter of law***. These facts are irrefutable, and as discussed in the analysis section, they act as a complete bar to this prosecution under Supreme Court law.

The rest, as they say, is history. Allergan, Inc. began to sell its newly-acquired product as BOTOX rather than Oculinum in 1992, and it abandoned the Oculinum trademark altogether on July 19, 2003. Id. at ¶ 36, Exhibit 35.

C. Toxin Research International, Inc. and the Four Botulism Illnesses in Florida

1. Toxin Research International and It's Fraud

From about at least 2003 until early 2006, Dr. Chad Livdahl and his wife, Dr. Zarah Karim, owned and operated three companies in Tucson, Arizona, including TRI. According to Government investigative reports supplied during discovery, in January 2003, Chad Livdahl contacted List Biological Laboratories, Inc. ("List") in Campbell, California, to inquire about the purchase of BoNT/A. Id. at ¶¶ 37 and 38, Exhibits 36 and 37. Purchasing under the name POWDERZ, Inc., Livdahl ordered custom-manufactured BoNT/A from List. The order required List to manufacture three different lots of BoNT/A, add a quantity of human albuman (supplied by Livdahl), and to package the resulting freeze-dried mixture into individual vials such that

each vial had 5 nanograms (5 billionths of a gram) of purified BoNT/A. Id. On or about May 15, 2003, List shipped 24 boxes of vials to Livdahl. Id.

Thereafter, Livdahl and Karim, under the guise of Toxin Research International, began to market the vials to physicians throughout the United States. Utilizing a mailing list of approximately twenty thousand people, Livdahl sent out thousands of TRI fliers advertising "an amazing offer" regarding "A Very Stable Clostridium Botulinum Toxin Type A." Id. at ¶ 39, Exhibit 38 (Mikhael grand jury transcript, 20:1 – 20:13); Id. at ¶ 7, Exhibit 6 (D'Entremont Certification, at ¶ 2, Exhibit 1). The list consisted of mainly practicing physicians, and Livdahl instructed his employees at TRI to add names of additional physicians and to remove the names of researchers and scientists from the mailing list. Id. at ¶ 39, Exhibit 38 (Mikhael transcript, 20:14 – 22:17). This is significant because Livdahl, on October 6, 2004, told an FDA investigator that TRI only sold its BoNT/A product to research institutions and licensed physicians conducting research. Id. at ¶ 40, Exhibit 39A (Johnson Certification, at ¶ 4).

According to the Government's own investigation, Livdahl and Karim then began to market their product directly to physicians by sponsoring conferences at which their product was showcased. Id. at ¶ 9, Exhibit 8 (U.S. v. Livdahl Complaint, at ¶¶ 24(a) – 24(e)). Moreover, according to the Government's own investigation, Livdahl and Karim represented to physicians that their product was "FDA approved," "awaiting FDA approval," and "generic Botox." Id. at ¶ 9, Exhibit 8 (U.S. v. Livdahl Complaint, at ¶ 28(g)); Id. at ¶¶ 3 and 4, Exhibits 2 and 3. Indeed, as the Government's investigation has revealed, Livdahl and Karim successfully created the impression to the physicians whom they were marketing that their BoNT/A was safe and ***legal*** to use. Id. at ¶¶ 2-7, Exhibits 1-6.

Even when physicians began to question the warnings on the label, Livdahl provided them with an explanation that was designed to overcome their concerns. Id. Livdahl went so far as to prohibit TRI employees from mentioning that his BoNT/A was not FDA approved to physicians/customers and to indicate that the warnings ("NOT FOR HUMAN USE") were for legal purposes. Id. at ¶ 39, Exhibit 38 (Mikhael Transcript, 11:21 – 12:18). As one former TRI employee testified to a Florida Federal Grand Jury:

> I don't believe that [Livdahl] told me right away, but later on, it was obvious that it was not FDA approved, and I believe he told me not to mention the fact that it was not FDA approved, and just that we had to write [the warnings] down for legal purposes.

Id. at ¶ 39, Exhibit 38 (Mikhael Transcript, 12:14 – 12:18).[2] According to Government agents, the day after one TRI employee provided her research to Livdahl demonstrating that TRI's BoNTA was required to meet FDA regulations and that approval was a lengthy process, Livdahl fired her. Id. at ¶ 40, Exhibit 39 (FDA S/A Perez Certification). Livdahl's scheme worked, and the Government's own documents show that he convinced ***over two hundred physicians and surgeons*** to purchase his BoNT/A, including Dr. Albert Poet, the defendant in this case. Id. at ¶ 41, Exhibit 40 (TRI customer and sales summary).[3]

The Government eventually sought, and obtained, an injunction against Livdahl and TRI from further marketing its BoNT/A. In the Government's pleadings, it stated that the "United States also seeks to protect individuals from defendants' false and misleading promotion, advertising, education, and treatment, representing and using Botulinum Toxin Type A as an FDA approved drug for human use." Id. at ¶ 9, Exhibit 8 (at page 23, ¶ 40). Without question, the "individuals" about whom the Government was referring were the physicians and surgeons

[2] It is important to note that this grand jury transcript, containing clearly exculpatory material, was not provided to the Defense by the Government.

[3] This document, too, was not provided to the Defense by the Government.

who, like Dr. Albert Poet, were duped by Livdahl's deception. Indeed, in its brief in support of injunctive relief, the Government said to the District Court:

> The potential for danger to the public is too great to allow defendants to continue to ship their product in interstate commerce, ***and to mislead individuals into thinking their product is one approved by the FDA***, or that is it safe for human use.

Id. at ¶ 42, Exhibit 41 (Government's Brief, at page 23). Thus, by the Government's own pleadings seeking an injunction restraining Livdahl from making further misrepresentations to "individuals," i.e. physicians (because he did not sell to patients), the Government argued to the District Court that Livdahl and TRI should be restrained from further misrepresentations. Id. The Government won, and ***it received a restraining order by clear and convincing evidence***. Id. at ¶ 43, Exhibit 42 (Detention Hearing Transcript, at 80:12 – 80:17). Livdahl was eventually convicted of conspiracy and mail fraud, and he was sentenced to 60 months in jail. Id. at ¶ 44, Exhibit 43. What did it take to incite the Government to stop Livdahl after over a year in business? A tragic incident, and Government agents have subsequently attempted to wrongfully and outrageously exploit it to their maximum advantage in the instant case.

2. Dr. Bach McComb and the Four Botulism Cases in Florida

In November 2004, Dr. Bach McComb's medical license was suspended, but he nonetheless was working as an employee at the Advanced Integrated Medical Center in Ft. Lauderdale, Florida. Id. at ¶ 42, Exhibit 41 (Government Brief, at page 7, n. 6). Ignoring his license suspension, McComb ordered raw BoNT/A directly from List, diluted it, and administered it to himself and three individuals on or about November 24, 2006. Id. Tragically for McComb and his three patients, McComb grossly under-calculated the amount by which he should have diluted the toxin. The result was that all four individuals, including McComb, were

stricken with botulism to such a degree that each required the assistance of mechanical ventilators despite the administration of antitoxin. All four individuals eventually recovered.

It is important to note that the FDA and Government Prosecutors knew, from at least as early as December 23, 2004, that TRI's BoNT/A was not involved in the four Florida botulism cases. Indeed, as acknowledged by the Government in its brief in support of a preliminary injunction, the Government stated:

> The Court should be aware, however, that the United States does not believe that the purported "Botox" used in this specific incident was TRI's product. Rather, it is the United States' belief that the purported "Botox" used to inject these four victims was a product manufactured by List Biological Laboratories, Inc. – a company not named in this lawsuit.

Id. at ¶ 42, Exhibit 41 (Government Brief, at page 7, n. 6). This distinction was repeated by a Government Prosecutor during Livdahl's detention hearing:

> Then, on November 30th, 2004, a national news story broke regarding four individuals, including Bach McComb, a co-defendant, and three others who had been injected with what purported at that time to be BOTOX had wound up with Botulism.
>
> Now, as it turned out, ***and I want to be very clear about this***, it was ***not*** [Livdal's and Karim's] product that caused that condition.

Id. at ¶ 43, Exhibit 42 (Detention Hearing Transcript, at 12:14 – 12:21) (emphasis added). The FDA's and the Government's knowledge is a significant point in this case.

3. The Path to Dr. Albert Poet

When investigators searched Advanced Integrated Medical Center on December 1, 2004, they discovered materials from TRI concerning its BoNT/A product. Id. This discovery, in turn, led to a search warrant at TRI's headquarters in Arizona on December 4, 2004. Id. Investigators discovered that computers seized from TRI's facility had been tampered such that files containing sales and customer information had been deleted. Id. at ¶ 42, Exhibit 41 (Government

Brief, at page 11-12). Investigators, however, were able to recover this data, and they learned that Dr. Albert Poet, along with over two hundred physicians and surgeons, had purchased TRI's product. Id.

D. The FDA's Investigation and Prosecution of Dr. Albert Poet

1. Investigation Leading to Indictment

On or about February 10, 2005, the FDA served Dr. Albert Poet with a Grand Jury subpoena requesting documents pertaining to his treatment of patients with BoNT/A. On or about March 3, 2005, Dr. Poet's prior counsel, Patrick T. Collins, Esq., produced over two thousand pages of records, including patient records, invoices, credit card statements, bank records, and appointment books. Id. at ¶ 45, Exhibit 44. On or about May 12, 2005, Attorney Collins supplemented the production with approximately five hundred additional documents relating to credit card authorizations and internal financial documents. Id.at ¶ 46, Exhibit 45. On or about June 6, 2005, FDA Special Agent Marc Hess and Assistant U.S. Attorney Hope Olds met with Attorney Collins and Dr. Poet for a proffer session. Id. at ¶ 47, Exhibit 46. Thereafter, between on or about July 12, 2005 and September 13, 2005, FDA Special Agent Marc Hess conducted interviews of at least approximately seven patients and one employee. On July, 13, 2006, the Government tendered a plea offer to Dr. Poet. Id. at ¶ 48, Exhibit 49. This plea was rejected at the end of July 2006.

On August 4, 2006, twenty months after the FDA obtained an injunction prohibiting the sales of TRI's BoNT/A, the FDA sent a letter to many (but not all) of Dr. Poet's patients advising them that "during the year 2004, you may have been ***exposed*** to an unapproved form of Botulinum Toxin Type A." Id. at ¶ 49, Exhibit 48 (emphasis added). Furthermore, the FDA urged the recipients to contact S/A Hess regarding their "***potential exposure***." Id. (emphasis

added). The letters to the patients were soon followed up by a second letter from the U.S. Attorney's Office informing the patients that "their name was forwarded to our office by law enforcement as a victim (or potential victim) . . ." of Dr. Poet. Id. at ¶ 50, Exhibit 49. The import of these letters was clear: the FDA and the Government – ***who made no attempt to advise or warn Dr. Poet's patients (whose identities they knew) in the year and a half they investigated him*** – suddenly warned his "victim" patients about their "exposure" to "unauthorized Botulinum Toxin" immediately after Dr. Poet rejected the plea offer and when they needed these patients as ***their*** witnesses (and not the defense's). In essence, it was an improper attempt to poison the witness well. The FDA's subsequent interviews of these witnesses are even more troubling.

2. S/A Hess' Interviews with Witnesses and the Prejudice to the Defense

Shortly after the FDA sent out the letters, S/A Hess started to interview Dr. Poet's patients. To encourage at least several of these patients to become witnesses favorable to the Government, S/A Hess engaged in improper deceptive practices. For instance, on or about August 25, 2006, S/A Hess called patient Debra V. O'Brien and ***told*** her that Dr. Poet had deceived her "by using a non-FDA approved substance rather than Allergan's brand of BOTOX®." Certification of Debra O'Brien, at ¶ 3. More troubling than this attempted coaching, S/A Hess went further by stating that "there were people in Florida who had been paralyzed and on ventilators ***from the same product that Dr. Poet used on [O'Brien]***." Id. at ¶ 4 (emphasis added). O'Brien informed S/A Hess that she did not feel that she had been deceived and that she intended to receive further treatment from Dr. Poet. Id. at ¶ 5.

S/A Hess' conduct is significant in three distinct ways. First, instead of inquiring ***whether*** the patient was a victim, he affirmatively stated and attempted to plant the seed in the

patient's mind that she indeed ***was*** a victim of deception. Second, and most troubling, S/A Hess affirmatively lied to the patient by telling her that people had been paralyzed and on ventilators from utilizing the same product that Dr. Poet had used on her. As stated previously, the FDA and the Government knew as early as December 23, 2005 – over twenty months previous – that the TRI product was not involved in the Florida botulism cases. Id. at ¶ 42, Exhibit 41 (Government Brief, at page 7, n. 6). Finally, ***S/A Hess included none of his statements to O'Brien, nor any of O'Brien's statements exculpating Dr. Poet, in his FDA Memorandum of Interview***. Hughes Cert. at ¶ 51, Exhibit 50. Accordingly, it is apparent that S/A Hess attempted to conceal his tactics to influence potential defense witnesses and to minimize exculpatory evidence. Unfortunately, this was not an isolated incident.

On August 15, 2006, S/A Hess interviewed called Theresa Buterick and informed her that "people in Florida had become sick using a product similar to that which Dr. Poet had used." Certification of Theresa Buterick, at ¶ 4. Buterick informed S/A Hess that she "did not believe that [she] was receiving Allergan's BOTOX® because Dr. Poet had indicated otherwise during [their] discussions." Id. at ¶ 6. Again, S/A Hess failed to mention in his report that he informed Buterick of the sicknesses in Florida, but he did state that Dr. Poet informed Buterick that he was not providing her with Allergan's product. Hughes Cert. at ¶ 52, Exhibit 51. As stated in his Memorandum of Interview, "Buternick [sic] ***did not*** believe that she was receiving the ***trademark*** drug named Botox because Poet had indicated otherwise during their discussions." Id. at page 2 (emphasis added). Most interestingly, ***the Government did not provide the Memorandums of Interview of either Buterick or O'Brien as part of its discovery, despite the fact that they contain exculpatory material***. The FDA's conduct, however, does not end there.

On July 12, 2005, S/A Hess surprised patient Shirley Spagnola by showing up at her residence to interview her. During their conversation, S/A Hess intimated that Spagnola could have gotten sick from the non-FDA approved botox that Dr. Poet used on her, and he said that "other people had received non-FDA approved botox had gotten sick or had died." Spagnola Certification, at ¶ 3. Spagnola informed S/A Hess of her trust in Dr. Poet and that she continues to trust him. Id. at ¶ 6. Again, S/A Hess did not mention in his Memorandum of Interview that he informed Spagnola about the four botulism cases in Florida. Hughes Cert., at ¶53, Exhibit 52.

Apparently, S/A Hess' efforts to influence the testimony of potential defense witnesses worked. On July 12, 2005, S/A Hess traveled to patient Joan Hall's residence and interviewed her concerning Dr. Poet's use of the TRI product. Over one year later, on July 31, 2006, Dr. Poet's office contacted Hall to request her consent to be interviewed by a Defense investigator, retired FBI Special Agent Ken Blankenbuehler. Hall returned the call to Dr. Poet's office and spoke directly with Dr. Poet, who took contemporaneous notes. Id. at ¶ 54, Exhibit 53. According to Hall, she became ill after her BoNT/A injections in December 2004. Id. Hall indicated that she "***spoke to [an] FDA official who blamed unapproved botox***." Id. (emphasis added). Furthermore, Hall indicated that she became "paralyzed on [the] right side of [her] face where [Dr. Poet] gave the [botox]." Id. (at page 2). Finally, Hall told Dr. Poet that the "***FDA experts said it was from unauthorized botox***." Id. (emphasis added). About three weeks later, on August 23, 2006, Hall called S/A Hess to tell him of her conversation with Dr. Poet. Hall told S/A Hess that she told Poet that he had "'almost killed' her with the previous Botox treatment." Id. at ¶ 55, Exhibit 54. Hall apparently ended her conversation with S/A Hess by stating that "she hoped that [Dr. Poet] had 'ill luck' with his life." Id. Nowhere in any of S/A Hess' reports

does he indicate that he advised Joan Hall of the source of her medical condition. Id. at ¶ 56, Exhibit 55.

Unfortunately, Hall wasn't the only witness who the Government potentially influenced. On August 10, 2006, S/A Hess called patient Theresa McCormick to interview her. During this conversation, S/A Hess told McCormick that the product that Dr. Poet used on her paralyzed people in Florida and that Dr. Poet paid less for the TRI product than Allergan's brand of BOTOX®. Blankenbuehler Certification, at ¶ 4. Apparently, McCormick told S/A Hess that she did not feel defrauded and did not mind receiving generic botox. Id. at ¶ 5. McCormick, however, "stated that she was very concerned about the FDA contacting her, attempting to make her a victim and attempting to frighten her by intimating that she could have gotten sick from her treatments." Id. at ¶ 6. Although she wanted to help Dr. Poet, she indicated that she did not want to testify in this matter, and she refused to sign a certification concerning her conversation with S/A Hess. Id. According to Blankenbuehler, who retired from the FBI after 34 years, "[b]ased on McCormick's attitude I felt that she was intimidated by the government's attempt to gain her cooperation by using scare tactics." Id.

Again, S/A Hess failed to mention in his Memorandum of Interview that he falsely told McCormick that people had been paralyzed in Florida from the same product that Dr. Poet used on her or that he informed her of the price that Dr. Poet had paid. Hughes Cert., at ¶ 57, Exhibit 56. Additionally, S/A Hess did not mention in his report that McCormick did not feel defrauded, but he did mention that McCormick stated that Poet "never pushed any treatment to her" and that she had "absolute trust" in Dr. Poet. Id. As with all of S/A Hess' other Memorandum's of Interview, the Government failed to provide this exculpatory information during discovery.

3. Indictment and the Government's Pretrial Discovery

At some point prior to August 24, 2006, the FDA recommended, and the U.S. Attorney's Office decided, to indict Dr. Albert Poet. It is important to note that ***at no time prior to August 24, 2006 did the FDA ever issue a Notice and Opportunity to Present Views as mandated by federal law and the accompanying regulations.*** 21 U.S.C. § 335; 21 C.F.R. § 7.84-7.86. On or about August 24, 2006, the Government obtained its Indictment against Dr. Poet for 13 counts of mail fraud (representing the 13 times he made purchases from TRI) in violation of 18 U.S.C. § 1341, and one count of felony misbranding, in violation of the Food, Drug and Cosmetic Act, 21 U.S.C. § 331(k), 333(a)(2) and 352(i). On September 5, 2006, the Court entered its standard Order for Discovery and Inspection. On or about September 3, 2006, the Government delivered its discovery pursuant to the Court's Order. Id. at ¶¶ 58 and 59, Exhibits 57 and 58 (discovery cover letter and index). On or about September 15, 2006, the Government supplemented its discovery production by notifying the defense of its intention to utilize Dr. Marc Kenneth Walton as its expert on certain matters. Id. at ¶ 60, Exhibit 59 (Walton designation).

Having used the Court's PACER system to view the Government's pleadings and certifications in the civil and criminal cases in Florida against Chad Livdahl and his company, TRI, the Defense immediately recognized that the Government failed to produce numerous documents which were exculpatory in that the ***Government previously indicated and submitted evidence tending to show that Livdahl and TRI committed fraud against the doctors to whom it sold their BoNT/A product***. Accordingly, the Defense wrote to the Government on September 28, 2006 to request that it provide all exculpatory materials. Id. at ¶ 61, Exhibit 60. The Government responded on September 30, 2006 that it had already produced all exculpatory materials. Id. at ¶ 62, Exhibit 61. On October 11, 2006, the Defense replied by reminding the

Government that its duty to provide exculpatory materials included not only documents in their possession, but also "documents in the possession of other government entities assisting in [the Government's] investigation." Id. at ¶ 63, Exhibit 62.

The Government responded on October 17, 2006 by producing well over one thousand pages of documents describing over 500 interviews with doctors, patients, medical employees, researchers and assorted individuals. Id. at ¶¶ 64 and 65, Exhibits 63 and 64 (discovery cover letter and index). Ten days later, on October 27, 2006, the Government produced an additional approximate ***two thousand to three thousand pages*** of discovery describing, among other things, more interviews with patients, doctors, researchers and assorted individuals; certain items obtained during the search warrants at TRI; invoices and financial records of TRI and various individuals and companies; scientific analyses results; e-mails and memos; and, medical records. Id. at ¶¶ 66 and 67, Exhibits 65 and 66.

Certainly, there were many items in the Government's supplemental discovery which contained evidence tending to exculpate Dr. Poet. See, e.g., id. at ¶¶ 2-6, Exhibits 1 through 5 (memo's of physician interviews describing Livdahl's fraudulent statements to deceive them into purchasing TRI's product). The vast majority of the documents, however, had no bearing whatsoever on this case, and it is apparent that the FDA agents simply transferred thousands upon thousands of pages of materials onto a computer disc. For instance, as the indexes indicate, there are ***literally*** hundreds of interview memorandums of individuals who were patients of other doctors located in other parts of the country. Id. at ¶¶ 66 and 64. Also included in the Government's production were other doctors' appointment books, time cards, bank account and credit card statements – all of individuals located in other parts of the country who and which have nothing to do with this case whatsoever. Id. Given the fact that the relevant documents

were included amongst a sea of irrelevant documents, it is obvious what the result would be upon the defense.

More troubling is what the Government failed to include in its vast production. The Government, for instance, produced none of its pleadings or memos which indicated that TRI was not responsible for the four botulism cases in Florida. Id. at ¶¶ 42 and 43, Exhibits 41 and 42 (Government's Brief in support of an Injunction and Detention Hearing transcript). Nor did the Government include a copy of the Government's certification indicating that a TRI employee had been fired after having advised Livdahl that the process to obtain FDA approval was quite lengthy. Id. at ¶ 40, Exhibit 39 (FDA S/A Perez Certification). Certainly, they were publicly filed documents, but the defense is nonetheless entitled to them. There were other exculpatory items, however, of which the Government had sole possession and control, and yet failed to produce to Dr. Poet.

For instance, the Grand Jury Testimony of Maryan Mikhael detailed how Livdahl instructed her to deceive physicians who called concerning TRI's BoNT/A. Id. at ¶ 38 (Mikhael Grand Jury Transcript). The Government did not produce the transcript in this case, nor did it produce the e-mails between Mikhael and Livdahl referenced in the testimony and in the Government's possession. In addition, there is a tape recording and a transcript of a conversation between Livdahl and Mikhael during which Livdahl may have attempted to influence Mikhael's statements to Government investigators. Id. at ¶ 68, Exhibit 67. This too was not produced.

What is most surprising, however, is the fact that the Government failed to produce ***any*** exculpatory witness statements of patients and employees in this case. As has already been demonstrated, S/A Hess' interview reports do contain ***some*** exculpatory information. Id. at ¶¶

51-53, 57, Exhibits 50 -52, 56. These, however, were not the only reports that contained exculpatory information. On August 28, 2006, S/A Hess called patient Donna Rice. Id. at ¶ 69, Exhibit 68. During this interview, Rice told S/A Hess that she had "complete trust" in Dr. Poet and that she saw "no difference between the FDA approved Botox cosmetic drug and the Toxin Research International (TRI) drug because the TRI drug was an 'unapproved generic.'" Id. Similarly, S/A Hess called patient Lois Dyer on August 10, 2006, and Dyer told S/A Hess that Dr. Poet "bombarded her with facts" during her consultation and that she would have told Dr. Poet to "go for it" if he thought the TRI product was the same as Allergan's. Id. at ¶ 70, Exhibit 69. Patient Susan Erickson told S/A Hess on July 12, 2005 that Dr. Poet provided an "extensive discussion" concerning the advantages and disadvantages of the treatments, as well as "possible side effects." Id. at ¶ 71, Exhibit 70 (Erickson Interview). Erickson said that Dr. Poet referred "to the drug with which he was treating her as both Botox and Botulinum Toxin" and that "she believes that FDA approval is not necessarily of vital importance for the safety of a particular drug because there are many drugs which are not yet FDA approved in Europe and have FDA approval pending." Id. The Government failed to produce any of these interviews.

Likewise, S/A Hess interviewed employees Heather Gifford, on August 9, 2006, and Laurie Toth, on July 18, 2006, prior to their grand jury testimony. Id. at ¶¶ 71-72, Exhibits 70-71. During these interviews, both employees stated that Dr. Poet indicated that the reason he was using it was that it was "purer than Botox." Id. Additionally, Toth stated that Poet said that the TRI product was "in the FDA process for approval." Id. This evidence tends to corroborate a good faith defense (he was a victim of TRI's fraud upon him) and negate state of the mind element necessary for conviction, i.e., ***this is clear evidence that Dr. Poet never intended to fraudulently deprive his patients of money, but rather his motivation for using the TRI product***

was for superior results. Both of these employees subsequently testified in the grand jury, but the Defense has not received either S/A Hess' Memoranda of Interviews nor the grand jury transcripts of potentially exculpatory information.

So one might ask how the Defense has all of this exculpatory material if the Government failed to produce it during discovery? The answer is that at least one Federal Prosecutor in the U.S. Justice Department has determined that all of the documents mentioned herein which the Government failed to produce in this case were materials subject to Brady. Hence, all of those materials were produced as exculpatory materials in another case, ***along with at least 26 additional memoranda of interviews of individuals and patients in the instant case***!

E. Summary

Having provided the Court with an extensive background on the substance, the other prosecutions, the investigation, and the conduct of the Government in this case, the Defense must now respectfully urge this Court to dismiss the indictment, with prejudice (and in the alternative without prejudice), based upon numerous legal grounds. The Defense argues that, as a matter of law, Counts One through Thirteen of the Indictment should be dismissed because the Congress has proscribed the conduct depicted in the Indictment under the Food, Drug and Cosmetic Act, and Counts alleging violations of 18 U.S.C. § 1341 are essentially duplicative of conduct the Congress specifically addressed. Second, it is also argued the Count must dismiss the Indictment, because the term "Botox is generic as a matter of law, and the Indictment therefore fails to state a claim. Additionally, the Defense submits that the Indictment must be dismissed on the grounds of equitable estoppel. In the alternative, the Defense argues that the Indictment must be dismissed ***at least without prejudice*** (but preferably with prejudice), for violation of due process. In the event the Court disagrees with the Defense, it is submitted that the Defense is

entitled to an Order directing the Government to review all of its evidence, nationwide, and produce all exculpatory evidence forthwith. Additionally, the Defense submits that it is entitled to Grand Jury transcripts. Further, the Defense submits that it is entitled to an exclusion of all Government witnesses interviewed by S/A Hess, and in the alternative, it is entitled to additional depositions and discovery pursuant to Fed. R. Crim. P. 15 and 17, including a list of every individual to whom the FDA and the Government sent a letter and who responded. In this regard, the Defense believes that it is entitled to a Bill of Particulars. It is respectfully submitted that the Defense is entitled to depositions and additional discovery under Fed. R. Crim. P. 15 and 17 of certain TRI former employees, certain physicians, and other individuals/corporations who possess information critical to Defense. Also, the Defense submits that it is entitled to an amendment of the Indictment to reflect Allergan Inc.'s true alleged mark, BOTOX® COSMETIC. Finally, the Defense requests that the Court designate this case as a 'complex case" under the Speedy Trial Act and exclude additional time thereunder.

LEGAL ANALYSIS

A. Overview of the Charges

1. What is *Not* Charged

It is important to note at the outset that ***there is no federal crime for utilizing a non-FDA approved substance in the care and treatment of patients.*** The reason is simple: Congress never intended the Food, Drug and Cosmetic Act to regulate the practice of medicine. See. United States v. Algon Chemicals, Inc., 879 F.2d 1154, 1159-60 (3d Cir. 1989). Indeed, the FDA's own interpretation of the legislative history of the act supports this proposition:

> Throughout the debate leading to enactment [of the Act], there were repeated statements that Congress did not intend the Food and Drug Administration to interfere with medical practice and references to the understanding that *the bill did not purport to regulate the practice of medicine as between the physician and*

> *the patient*. Congress recognized a patient's right to seek civil damages in the courts if there should be evidence of malpractice, and declined to provide any legislative restrictions upon the medical profession.

FDA Policy Statement, 37 Fed. Reg. at 16503 (emphasis added). As one former Chief Counsel to the FDA has stated:

> Not only does the legislative history fail to show a Congressional intent that this be used to restrict the conditions for which physicians might prescribe drugs, but it flatly contradicts any such interpretation. In enacting the 1938 Act Congress clearly intended to avoid impinging on the practice of medicine.

Hutt, Regulation of the Practice of Medicine Under the Pure Food & Drug Laws, 33 A. of Food & Drug Officials Q. Bull. 3, 7 & 9 (1969). There is also a common sense element to this proposition: if there were a crime to utilize a non-FDA approved substance, the FDA would undoubtedly charge Dr. Poet with it. The Food, Drug and Cosmetic Act, however, ***does*** regulate the sale and flow of drugs, both approved and unapproved, in interstate commerce. In this regard, Congress created a statutory scheme to empower the FDA to "enforcing its right under the Act to control the supply of unapproved drugs in interstate commerce." Algon, 879 F.2d at 1161. The end result of this Congressional enactment is that the "United States Food and Drug Administration [is] the federal agency within the United States Department of Health and Human Services charged with the responsibility of protecting the health and safety of the American public by assuring that drugs are safe and effective for their intended uses before they may be legally introduced into interstate commerce." Indictment, at ¶ 2(a).

2. Mail Fraud

Counts One through Thirteen of the Indictment allege that Dr. Poet committed mail fraud, in violation of 18 U.S.C. § 1341. Tracking the exact language of the statute, the accusation alleges that Dr. Poet "did knowingly and willfully devise a scheme and artifice to defraud . . . and to obtain money and other property by means of fraudulent pretenses,

representations, and promises, and for the purpose of executing such scheme and artifice knowingly caused to be delivered by private and commercial interstate carrier according the direction thereon, matters and things, as more fully described below." Indictment, at ¶ 5. Although the Indictment alleges several items which were parts of Dr. Poet's "scheme and artifice," the real crux of the FDA's fraud case is that Dr. Poet injected "fake Botox" into his patients:

> It was further part of the scheme and artifice to defraud that defendant ALBERT POET injected many of the approximately 130 patients who sought ***Botox***® treatments at his offices between January 1, 2004 and December 1, 2004 with Tritox.

Id. at ¶ 14 (emphasis added). The Indictment describes "Botox®" as "the brand name of a drug derived from Botulinum Toxin Type A and for the treatment of certain muscle disorders of the eye that was manufactured by Allergan, Inc, of Irvine, California." Id. at ¶ 3(d). Each of counts One through Thirteen represents each occasion that Chad Livdahl and his company, TRI, sent vials of its BoNT/A to Dr. Poet through overnight carrier.

3. Felony Misbranding

Count Fourteen alleges that Dr. Poet committed felony misbranding by offering TRI's BoNT/A as "Botox® and Botox® Cosmetic. . ." after it had been shipped in interstate commerce. Id. at page 10. Misbranding is wholly a creature of the Food, Drug and Cosmetic Act, 21 U.S.C. § 301, et. seq. The *definition* of misbranding referenced in the indictment appears at 21 U.S.C. § 252(i):

> A drug or device shall be deemed to be misbranded—
>
> * * * * *
>
> (i) (1) If it is a drug and its container is so made, formed, or filled as to be misleading; or (2) ***if it is an imitation of another drug; or (3) if it is offered for sale under the name of another drug***.

Id. (emphasis added). The actual prohibition of misbranding is found in 21 U.S.C. § 333(k):

> The following acts and the causing thereof are prohibited:
>
> * * * * *
>
> (k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

Id. There is another important aspect to this charge: Congress fashioned a statutory scheme such that varying degrees of criminal intent result in increased penalties. Under 21 U.S.C. § 333(a):

> (1) Any person who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than $1,000, or both.
>
> (2) Notwithstanding the provisions of paragraph (1) of this section, if any person commits such a violation after a conviction of him under this section has become final, ***or commits such a violation with the intent to defraud or mislead***, such person shall be imprisoned for not more than three years or fined not more than $10,000, or both.

Id. (emphasis added). Hence, it is clear Congress created a fraud statute specifically designed to address the crime of fraud with respect to drugs regulated under the Food, Drug and Cosmetic Act.

B. POINT 1: Counts One through Thirteen Must be Dismissed Because the Congress has Determined that Fraud Crimes Involving Drugs Regulated by the FDA must be Prosecuted under the Food, Drug and Cosmetic Act, and the Supreme Court has Mandated that where Congress has Defined a Particular Crime, the Government cannot Proceed with Prosecution Under a Different Statute

1. Congress' Legislative Scheme and its History

a. The Pure Food and Drug Act of 1906

The criminal portions of today's Food, Drug and Cosmetic Act trace their roots to the first Congressional Act regulating the interstate sale of medicinal treatments, the Pure Food and

Drug Act of 1906, c. 3915, Pub. L. No. 59-384, 34 Stat. 768 (1906) (repealed 1938). Originally a misbranding statute, the 1906 Act only regulated drugs by requiring that they be labeled correctly in that they not be "misbranded." Id. In defining "misbranding," the Congress stated that term applied:

> . . . to all drugs, or articles of food, . . . the package or label of which shall bear any statement, design, or device regarding such article, or the ingredients or substances contained therein which shall be ***false or misleading in any particular***, and to any food or drug product which is falsely branded as to the State, Territory, or country in which it is manufactured or produced. . . . An article shall also be deemed to be misbranded: ***In case of drugs: First. If it be an imitation of or offered for sale under the name of another article. Second. [In case of a substitution of contents,] or if the package fail to bear a statement on the label*** of the quantity or proportion of any alcohol, morphine, opium, cocaine, heroin, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate, or acetanilide, or any derivative or preparation of any such substances contained therein.

Id. at § 8 (emphasis added). Under Section 4 of the Act, Congress required that upon determination that any article may be misbranded, "notice shall be given to the party from whom the sample was obtained. Any party so notified shall be given an opportunity to be heard." Id. at § 4. If the Secretary of Agriculture (then the primary regulatory agency) then determined that a violation had occurred, it was required to then certify the results of the inquiry and forward the matter to the U.S. Attorney's Office. Id. at § 5. Finally, the actual enforcement provisions of the 1906 Act imposed a ***misdemeanor penalty*** for violations of the Act. Id. at § 2.

Two points are worthy of note. First, the Supreme Court has noted that the Act's provision of an administrative hearing prior to presentation to the U.S. Attorney's Office made sense in that "the determination whether an article is misbranded is left to the Bureau of Chemistry of the Department of Agriculture, which is most natural if the question concerns ingredients and kind, but hardly so as to medical effects." United States v. Johnson, 221 U.S. 488, 498 (1911). And second, as the Supreme Court noted, no regulatory agency at the time was

equipped to address any claims or statements regarding the efficacy of any particular drug. Id. Hence, the term "misbranding" could not apply to medicinal effects. Id.

b. The Food, Drug and Cosmetic Act of 1938

The 1906 act was subsequently superseded by the Food, Drug and Cosmetic Act of 1938, ch. 675, 52 Stat. 1040 (1938), now codified as 21 U.S.C. § 301 et. seq. Some of the major components of the revisions included vesting the Food and Drug Administration – an agency created in July 1930 from the Bureau of Chemistry – with the authority to "promote the public health by promptly and efficiently reviewing clinical research ***and taking appropriate action on the marketing of regulated products in a timely manner***. . . ." 21 U.S.C. § 393(b)(2) (emphasis added). The 1938 Act preserved the requirement that any person accused of misbranding under the Act is entitled to a hearing before the Commissioner prior to any recommendation of prosecution:

> Before any violation of this chapter is reported by the Secretary to any United States attorney for institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views, either orally or in writing, with regard to such contemplated proceeding.

21 U.S.C. § 335 (ch. 675, Sec. 305, 52 Stat. 1045 (1938)). Additionally, Section 2 of the 1906 Act was replaced by a new criminal provision which contained increased penalties based upon the level of intent of the accused. 21 U.S.C. § 331(a) (June 25, 1938, ch. 675, Sec. 303, 52 Stat. 1043 (1938)). Under the general intent provisions, any person who violated the Act was subject to a misdemeanor conviction. Id. (original subsection (a) of the Act). The Congress, however, included a second tier which imposed a felony conviction of up to three years imprisonment for individuals who "commit[] such a violation with the intent to defraud or mislead. . . ." Id. (original subsection (b) of the Act).

The legislative history of the amendments makes clear that it was Congress' intent that the FDA was to use the criminal penalty provisions to protect the consumer. The House Committee report stated that the Act "seeks to set up effective provisions against abuses of consumer welfare growing out of inadequacies in the Food and Drugs Act of June 30, 1906." H. Rep. No. 2139, 75th Cong., 3rd Sess., at 1. Similarly, the Senate Committee emphasized that the new law "must not weaken the existing laws. . . . [rather] . . . it must strengthen and extend that law's protection of the consumer." S. Rep. No 152, 75th Cong, 1st Sess., at 1. To this end, the Congress wanted to ensure that the criminal penalties were increased so as to prevent the civil and criminal fines prescribed under the 1906 Act from becoming a cost of doing business. In the House Committee's own words, the legislation "increases substantially the criminal penalties . . . which some manufacturers have regarded as substantially a license fee for the conduct of an illegitimate business." H. Rep. No. 2139, 75th Cong., 3d Sess., at 4. Hence, it is clear that in enacting the Food, Drug and Cosmetic Act of 1938, the Congress expressed its clear intent to protect the consumer from fraudulent practices relating to drugs through the new criminal provisions of the Act.

c. Subsequent Revisions

The criminal provisions of the Food and Drug Act of 1938 have been amended fifteen times since the Act's initial passage. See 21 U.S.C. § 331 (legislative history). In 1965, the Act's criminal provisions were amended to include increased penalties for depressants and stimulants, and these penalties were increased further in 1968. Pub. L. 89-74, Sec. 7(a) (1965); Pub. L. 90-639 (1968). The narcotics and stimulants provisions were thereafter excised in 1970 and transferred to what is now 21 U.S.C. § 801, et seq. Pub. L. 91-513 (1970). Most relevant, however, is that Congress re-designated the second offense and fraud provisions into section (b)

in 1970, and re-designated them again into its current form in 1988. Pub. L. 91-513 (1970); Pub. L. 100-293 (1988). ***The significance of this history is that the Congress had the ability to amend the original 1938 Act, actually used that ability, but did not expand the purview of the criminal portions to include the applicability of any other criminal statute under Title 18 to address fraudulent conduct with respect to drugs regulated under the Act***.

2. United States v. Dowling and its Progeny

a. Dowling

The Supreme Court's decision in Dowling v. United States, 473 U.S. 207 (1985), stands for the propositions that: 1) criminal statutes are to be read narrowly and harshly against the Government; and 2) ***the Government cannot utilize other criminal statutes to prosecute particular conduct when the Congress has clearly spoken as to which criminal statutes (and corresponding penalties) apply to that conduct***. In Dowling, the defendants were convicted of interstate transportation of stolen property, 18 U.S.C. § 2314, by manufacturing and shipping "bootleg" copies of Elvis Presley recordings. Id. at 209-10. The defendants appealed, claiming that their convictions were in error because the Congress required that their conduct be punished under the copyright laws, 17 U.S.C. § 506, and not under 18 U.S.C. § 2314. Id. at 212. The Ninth Circuit upheld the district court's decision, 739 F.2d 1445 (9th Cir. 1984), but the Supreme Court reversed the conviction.

In so holding, the Court first noted that it is the Congress which defines the conduct that constitutes federal crimes and prescribes the corresponding punishment. Id. at 213-14. As such, when construing the boundaries of federal criminal statutes, the Court stated that the "Rule of Lenity" applies. Id. at 213, 229. Specifically, the Court noted that "[d]ue respect for the prerogatives of Congress in defining federal crimes prompts restraint in this area, where we

typically find a 'narrow interpretation' appropriate." Id. at 213 (citing Williams v. United States, 471 U.S. 419, 424 (1985)). Quoting Chief Justice Marshall, the Court emphasized need to strictly interpret federal criminal statutes:

> The rule that penal laws are to be construed strictly, is perhaps not much less old than construction itself. It is founded on the tenderness of the law for the rights of individuals; and on the plain principle that the power of punishment is vested in the legislative, not in the judicial department. It is the legislature, not the Court, which is to define a crime, and ordain its punishment.

Id. at 213-14 (quoting United States v. Wiltberger, 5 Wheat. 76, 95 (1820)).

The Court then proceeded to note that the defendants' conduct fit within the purview of 18 U.S.C. § 2314, "but awkwardly" so. Id. at 218. As a result, the Court stated that "when interpreting a criminal statute that does not explicitly reach the conduct in question, we are reluctant to base an expansive reading on inferences drawn from subjective and variable 'understandings.'" Id. (quoting Williams, 458 U.S. at 286). The Court then proceeded to examine the legislative history of the copyright laws. Id. at 221-22. Noting that Congress acted with "exceeding caution" in fashioning criminal penalties for copyright, the Court concluded that the resulting criminal statutes demonstrated that "Congress carefully calibrated the penalty to the problem. . . ." Id. at 222. Accordingly, the Court stated that Congress' intentional and specific actions to define the conduct warranting punishment for copyright violations "provide a final and dispositive factor against reading § 2314 in the manner suggested." Id. at 226. As a result, the Court reversed the convictions, stating:

> the deliberation with which Congress over the last decade has addressed the problem of copyright infringement for profit, as well as the precision with which it has chosen to apply criminal penalties in this area, demonstrates anew the wisdom of leaving it to the legislature to define crime and prescribe penalties.

Id. at 228.

b. Subsequent Cases

A district court in United States v. LaMacchia, 871 F. Supp. 535 (D. Mass. 1994) subsequently applied Dowling to prohibit copyright infringement prosecutions under the wire fraud and mail fraud statutes. In so holding, the court noted that the Government's theory that wire fraud and mail fraud were different than the statutes prohibiting interstate shipment of stolen property would "produce the same pernicious result that Justice Blackmun warned of in Dowling, of ***permitting the government to subvert the carefully calculated penalties of the Copyright Act by selectively bringing some prosecutions under the more generous penalties of the mail and wire fraud statutes***." Id. at 544 (emphasis added).

Two other district courts, both in the Third Circuit, cited Dowling as additional justification for dismissing charges. In United States v. Brooks, 945 F. Supp. 830 (E.D.Pa. 1996), District Judge Cahn dismissed an indictment against the defendant which charged him with four counts of copyright infringement and one count making of false statements, in violation of 18 U.S.C. § 1001. Although the court dismissed the indictment on other grounds, the judge stated that Dowling provided additional justification for dismissing the false statements count. Id. at 834, n.9. Specifically, the Judge stated that Section 1001 was "broad and general," and Dowling underscored the necessity of honoring Congressional intent when the Congress acts with precision:

> In light of the Supreme Court's language in Dowling about the uniqueness of copyright and the care with which Congress drafted the criminal provisions of the Copyright Act, this Court does not see how the Government can proceed against Brooks under both § 1001 and the Copyright Act.

Id. As a result, the Court stated that "***[t]his is in essence a copyright infringement action, and the government must proceed within the limits of the criminal provisions of the Copyright Act as drafted by Congress***." Id. (emphasis added).

In United States v. Alsugair, 256 F. Supp.2d 306 (D. NJ 2003), then Judge Orlofsky found that the counts in an indictment charging the defendant of mail fraud were defective because they failed to adequately describe copyright infringement. Id. at 315. In so holding, the court noted, with approval, that it was doubtful that any copyright infringement claims could be alleged under mail fraud because of the decisions in Dowling and LaMaccia. Id. at 315, n. 10. "Otherwise, the Government could punish a defendant for a copyright violation under the mail-fraud statute when the violation would not constitute criminal conduct under the Copyright Act." Id.

3. Dowling's Applicability to Misbranding and the Instant Case

In the instant case, it is clear that the Congress intended to establish a statutory scheme to address the exact conduct charged by the Indictment in the instant case. Indeed, 21 U.S.C. §§ 331, 333, 252 and 253 cover ***every*** possible manner in which a drug may be misbranded and dispensed to a patient, be it by mail, common carrier or by personal delivery. In fact, it is apparent that the original 1906 Act was established in response to ***a Supreme Court holding that the Postmaster General's mail fraud statutes could not address the claims and representations made in medicinal advertisements in postal mailings***. American School of Magnetic Healing v. McAnnulty, 187 U.S. 94 (1902). In that case, the Postmaster General, on the basis of the original mail fraud statutes, refused to deliver certain advertisements relating to efficacy of electromagnetic treatments. Id. at 103-04. In holding that the Postmaster General did not have the statutory authority to make decisions relating to the efficacy of medicinal treatments, the Court stated:

> As to the effectiveness of almost any particular method of treatment of disease is, to a more or less extent, a fruitful source of difference of opinion, even though the great majority may be of one way of thinking, the efficacy of any special method

> ***is certainly not a matter for the decision of the Postmaster General within these statutes relative to fraud***.

Id. at 105 (emphasis added). Accordingly, the Court held that the Postmaster General's action of utilizing the mail fraud statutes to refuse to deliver certain medicinal advertisements was "not one which by any construction of those facts is covered or provided for by the statutes under which the Postmaster General has assumed to act. . . ." Id. at 109-10.

Congress enacted the Pure Food and Drug Act of 1906 in response to this case and the ineffectiveness of the other statutes to address fraudulent claims in medicinal treatments. In so doing, the Congress included, in the original act, provisions imposing criminal penalties for ***shipment or delivery for shipment***, of misbranded articles between states. c. 3915, Pub. L. No. 59-384, 34 Stat. 768, § 2 (1906) (repealed 1938). It is important to note that this section demonstrates Congress' intent to ***address the conduct*** of not only the physical transportation of misbranded goods by the offender, ***but also the interstate shipment of misbranded goods by common, private, carrier***:

> Sec. 2. That introduction into any State . . .from any other State . . . of any article of food or drugs which is adulterated or misbranded, within the meaning of this Act, is hereby prohibited; and any person who shall ***ship or deliver for shipment*** from any State . . . to any other State . . . or who shall receive in any State . . . ***and having so received shall deliver, in unbroken packages, for pay or otherwise***, or ***offer to deliver to any other person***, any such article so adulterated or misbranded within the meaning of this Act . . . shall be guilty of a misdemeanor. . .

Id. (emphasis added). Indeed, the Supreme Court has acknowledged Congress' intent in the 1906 Act to place the onus of criminal "risk on shippers with regard to the identity of their wares." United States v. Johnson, 221 U.S. 488, 497-98 (1911). By contrast, the revisions of the original mail fraud statutes in 1909 did not include any provision for either drugs – in response to the Supreme Court's decision – ***or for the application of the act to private commercial carriers***. (Mar. 4, 1909, ch. 321, Sec. 215, 35 Stat. 1130). In fact, it was not until 1994 that Congress saw

fit to include private commercial carriers in the language of the mail fraud statute. See 18 U.S.C. § 1341 (statutory history detailing 1994 amendments).

Congress' intent to address conduct relating to misbranded drugs under Title 21 is further underscored by the 1938 amendments, which retained the provisions relating to interstate shipment by common (private) carrier, 21 U.S.C. § 331(c), but also broadened the Act's application to the receipt, delivery, and sale of misbranded and counterfeit drugs generally.[4] United States v. Dotterweich, 320 U.S. 277, 280 (1943) ("By the Act of 1938, Congress extended the range of its control over illicit and noxious articles and stiffened the penalties for disobedience."). Congress also retained former Section 4 of the 1906 Act, which required an administrative hearing before the Secretary recommended any criminal prosecutions under Act. 21 U.S.C. § 335. Hence, not only did Congress prescribe the penalty, it also prescribed the means by which it wanted the Act enforced. Johnson, 221 U.S. at 498 (Noting that Section 4 of the Act requires a misbranding determination by the Bureau of Chemistry, "which is most natural".). In this regard, Congress' statutory scheme left it to the FDA, and not the U.S. Attorney or the U.S. Postal Service, to determine whether a drug was misbranded, and Congress gave the FDA very specific criminal tools ***and procedures*** to use in enforcing the Act.

Most relevant, however, is that Congress broadened the ambit of § 331(k) – the sub-paragraph with which the defendant has been charged – by making it unlawful to ***sell*** a misbranded drug "after ***shipment*** in interstate commerce". 21 U.S.C. § 331(k). The Congress ***did not*** use the words transportation, travel, or ***receipt***. Rather, they used a term which has always been associated with the use of private commercial carriers, ***shipment***. See Sproles v.

[4] Congress' intent to address most criminal violations relating to drugs under Title 21 rather than Title 18 is further demonstrated by Congress' addition of paragraph (q) in 1976 and paragraph (w) in 1996, which made it a crime to make certain false statements to the FDA, an executive agency. 21 U.S.C. § 331 (legislative history). These crimes are already covered under 18 U.S.C. § 1001.

Binford, 286 U.S. 374, 393 (1932) (holding that "'common carrier receiving or loading points,' and the unloading points, described, seem quite clearly to be points at which ***common carriers*** customarily receive ***shipments***, of the sort that may be involved, for transportation, or points at which ***common carriers*** customarily unload such ***shipments***."). Hence, it is clear that the fraudulent misbranding charge under Count 14 of the Indictment requires the Government to prove, in addition to ***fraudulent intent***, a "shipment" be made by ***common carrier***, and then an offering of sale (for ***money***) a drug which contains a ***false statement***.

In this regard, it is then apparent that the elements for Counts One through Thirteen of the Indictment – Fraud and Swindles Through Use of Interstate Carrier in violation of 18 U.S.C. § 1341 – are identical and duplicative (i.e. double jeopardy) to those of misbranding under Title 21.[5] Blockburger v. United States, 284 U.S. 299, 304 (1932) ("Where the same act or transaction constitutes a violation of two distinct statutory provisions, the test to be applied to determine whether there are two offenses or only one is whether each provision requires proof of a fact which the other does not."); see also United States v. Hodge, 211 F.3d 74, 78 (3d Cir. 2000) ("To determine whether the offenses grow out of the same occurrence, we apply the test set forth in Blockburger."). Indeed – as a practical matter – the Government must necessarily turn to the results of the FDA process of drug approval to demonstrate the veracity, or falsity, of Dr. Poet's representations to his patients – a process that did not exist prior to 1906. See McAnnulty, 187 U.S. 94 (1902). Given, 1) the legislative history demonstrating that Congress has "carefully calibrated the penalty to the problem," 473 U.S. at 222; 2) the Supreme Court precedents both before and after the 1906 Act; and, 3) the fact that the elements under the Title 21 and Title 18 crimes are now identical, Dowling requires that this Court invoke the "'time-

[5] The Government need prove no additional fact to obtain a conviction under 18 U.S.C. § 1341 once it has satisfied its burden under 21 U.S.C. §§ 331(k), 333(a)(2) and 252(i).

honored interpretive guideline' that "ambiguity concerning the ambit of criminal statutes should be resolved in favor of lenity. . . ." Dowling, 473 U.S. at 229 (wuoting Liparota v. United States, 471 U.S. at 427)).

Accordingly, it is respectfully submitted that Counts One through Thirteen must be dismissed with prejudice because the Congress has specifically defined the conduct constituting the crime under 21 U.S.C. §§ 331, 333 and 252.

C. POINT 2: The Court Must Dismiss The Indictment Because the Term "Botox" is Generic as a Matter of Law, and the Government Cannot Prove Fraud through the Use of the Generic Term

The starting point for the analysis is the Food, Drug and Cosmetic Act itself, which clearly indicates Congress' intent that the Act should not trump the Trademark laws. Indeed, in 21 U.S.C. § 358, Congress gave the FDA the ability to designate the official names for approved drugs. This same statute, however, limits the FDA's powers by prohibiting the FDA from designating a name which has trademark protection. "In no event, however, shall the Secretary establish an official name so as to infringe a valid trademark." 21 U.S.C. § 358(a). With this background, the trademark laws clearly demonstrate that the term "Botox" is generic, therefore rendering Allergan, Inc.'s registration as invalid – and Dr. Poet's use of the word entirely legal.

1. Trademark Law and Genericness

a. Trademark Statutes

Under 15 U.S.C. § 1052(e)(5), no trademark can issue, under any circumstances, for any mark which "comprises any matter that, as a whole, is functional." This is also known as "genericness." Congress' intent to refuse trademark protection on generic marks is also seen in 15 U.S.C. § 1065, which generally declares registered trademarks incontestable after five years, except "no incontestable right shall be acquired in a mark which is the generic name for the

goods or services or a portion thereof, for which it is registered." 15 U.S.C. § 1065(4). In the words of Judge Friendly:

> A generic term is one that refers, or has come to be understood as referring, to the genus of which the particular product is a species. At common law neither those terms which were generic nor those which were merely descriptive could become valid trademarks, see *Delaware & Hudson Canal Co. v. Clark*, 80 U.S. (13 Wall.) 311, 323, 20 L. Ed. 581 (1872) ("Nor can a generic name, or a name merely descriptive of an article or its qualities, ingredients, or characteristics, be employed as a trademark and the exclusive use of it be entitled to legal protection").

Abercrombie & Fitch Co. v. Hunting World, Inc., 537 F.2d 4, 9 (2nd Cir. 1976); see also, Park 'n Fly v. Dollar Park and Fly, Inc., 469 U.S. 189, 194 (1985) (adopting definition of "generic"). As demonstrated by the Act itself, "no matter how much money and effort the user of a generic term has poured into promoting the sale of its merchandise and what success it has achieved in securing public identification, it cannot deprive competing manufacturers of the product of the right to call an article by its name." Id. Accordingly, under no circumstances may a generic term be trademarked.

Congress placed the onus on trademark applicants to demonstrate why their mark is unique by requiring them to provide the Commissioner of Trademark with all of the information necessary for the U.S. Patent and Trademark Office, and not the applicant, to make the determination of protectability. In this regard, 15 U.S.C. § 1051 requires the applicant to make a statement to the Commissioner of Trademark, ***under oath***, concerning the use of the mark prior to the application:

> (3) The statement shall be verified by the applicant and specify that—
>
> (A) the person making the verification believes that he or she, or the juristic person in whose behalf he or she makes the verification, to be the owner of the mark sought to be registered;
> (B) to the best of the verifier's knowledge and belief, the facts recited in the application are accurate;
> (C) the mark is in use in commerce; and

> (D) to the best of the verifier's knowledge and belief, no other person has the right to use such mark in commerce either in the identical form thereof or in such near resemblance thereto as to be likely, when used on or in connection with the goods of such other person, to cause confusion, or to cause mistake, or to deceive, except that, in the case of every application claiming concurrent use, the applicant shall—
> (i) state exceptions to the claim of exclusive use; and
> (ii) shall specify, to the extent of the verifier's knowledge--
> (I) any concurrent use by others;
> (II) the goods on or in connection with which and the areas in which each concurrent use exists;
> (III) the periods of each use; and
> (IV) the goods and area for which the applicant desires registration.

15 U.S.C. § 1051(a)(3).

b. A Mark can Become Generic After Registration

It is also important to note that even if a mark is not generic prior to registration, it can nonetheless become generic after its registration, thus voiding its protection and registration. In the seminal case Singer Mfg. Co. v. June Mfg. Co., 163 U.S. 169 (1896), the Supreme Court held that Singer's actions of associating its name with a sewing machine rendered the mark "Singer" generic after the patent on the machine had expired, thus permitting competitors a limited right to use "Singer" in the advertisements of their products. This decision eventually applied to trademark law, where Learned Hand held that Beyer's own conduct rendered its trademark on "Aspirin" invalid as to consumers for genericness:

> . . . when, as here among consumers, a mark does not give even an intimation of the owner, there is no room at all for any protection. . . . . After all presumptions and other procedural advantages have been weighed, the owner must show that his mark means him, else he cannot prevent others from using it.

Beyer Co. v. United Drug Co., 272 F. 505, 513 (S.D.N.Y 1921); see also, Am. Thermos Products Co. v. Aladdin Industries, Inc., 207 F. Supp 9 (D. Conn. 1962) (invalidating the trademark on "Thermos" because of genericness). At the crux of the issue is how the general consuming public views the term and whether there are alternative means to describe the product or service.

A.J. Canfield Co. v. Honickman, 808 F.2d 291, 305-06 (3rd Cir. 1986); Genessee Brewing Co. v. Stroh brewing Co., 124 F.3d 137, 144 (2nd Cir. 1997).

In this regard, a district court in the Southern District of New York invalidated the trademark on "Pilates" in 2000 for genericness. Pilates, Inc. v. Current Concepts, Inc., 120 F. Supp.2d 286 (S.D.N.Y. 2000). In so doing, the court outlined in great detail the types of evidence to be considered in determining whether a mark is generic: "(1) dictionary definitions; (2) generic use of the term by competitors and other persons in the trade; (3) [the trademark registrant's] own generic use; (4) generic use in the media; and (5) consumer surveys." Id. at 297. These factors prove significant in the instant case.

2. The Term Botox was Generic Before Allergan, Inc. Applied for its Registration

a. Allergan, Inc.'s Registration and Prior Generic Use

As demonstrated by Exhibits 13 through 30 attached to the Certification of William J. Hughes, Jr., the term "Botox" was used as a generic contraction for Botulinum Toxin long before Allergan, Inc. applied for its trademark. In each of these articles, "Botox", "BOTOX" and "BoTox" is used to denote generic botulism toxin. In fact, one article submitted for publication in August 1990 detailing the results of a study mentions the name of the company from whom the "BOTOX" was obtained, Oculinum Inc.. Hughes Cert., at ¶ 25, Exhibit 24. Further, the American Academy of Otolarynology-Head and Neck Surgery approved the use of "Botox" in July 1990 for the use in head and neck dystonias – a year and a half before Allergan, Inc. applied for the mark and three months before Allergan swore it was first used. Id. at ¶ 24, Exhibit 23.

The significance of these articles, which are the result of limited research, is twofold. First, Allergan, Inc. submitted applications for the registration of the BOTOX trademark in 1991 and 1992 indicating, under oath, that the first use of BOTOX was in September 1990. Id. at ¶¶

34-35, Exhibits 33 and 34. The medical journal articles, many of which are authored by physicians who subsequently became Allergan, Inc. researchers and employees, show otherwise. As a result, it is evident that Allergan, Inc.'s trademark on BOTOX is invalid and unenforceable. Medinol Ltd. v. Neuro Vasx, Inc., 67 U.S.P.Q.2d 1205, 1209 (T.T.A.B. 2003) ("A trademark applicant commits fraud in procuring a registration when it makes material representations which it knows or should know to be false or misleading."); Metro Traffic Control, Inc. v. Shadow Network, Inc., 104 F.3d 336, 340 (Fed. Cir. 1997). The rationale is simple, it is up to the PTO, and not the applicant, to determine whether a mark is protectable or generic. The second impact is that, aside from Allergan, Inc.'s untrue statements to the U.S. PTO, the prior generic use of the term Botox renders the trademark invalid as a matter of law. See Pilates, Inc., 120 F. Supp.2d 286; Beyer, 272 F. 505, 513; Metro Traffic, 104 F.3d at 339 (prior use grounds for invalidating trademark).

b. Application to the Instant Case

It is respectfully submitted that the genericness of the term Botox renders the trademark invalid as a matter of law. ***As a result, Dr. Poet was, and is, free to use the term in its generic sense***. As Paragraph 4(b) of the Indictment concedes, Dr. Poet utilized a product that contained Botulinum Toxin Type A. By utilizing the term generic Botox to denote Botulinum Toxin Type A, Dr. Poet could only have defrauded his patients if the substance he provided to his patients did not contain any BoNT/A.[6] The Indictment does not allege this. Accordingly, by the

[6] Certainly the Government will argue that the issue is what Dr. Poet's patients believed they were receiving. This is an incorrect analysis because if Dr. Poet was legally able to utilize the term Botox to refer to Botulinum Toxin, then his usage of that term in that sense cannot form the basis of any fraud prosecution so long as BoNT/A was used. In this regard, it is state law, not federal law, which governs a doctor's duty to inform his patients, and in New Jersey, there is no duty to inform a patient of the FDA status of a particular drug or device if the physician believes that such drug or device has obtained some level of FDA approval. Blazoski v. Cook, 346 N.J. Super. 256, 273 (App. Div. 2002) ("We hold that defendant was not required to disclose to plaintiff the FDA investigational status of pedicle screws. . . .").

Indictment's own terms, the Government cannot present any fact or sets of facts which could result in a conviction under the statutes charged.

Accordingly, it is respectfully submitted that the Court must dismiss the Indictment, with prejudice, in its entirety. Certainly, this is an extreme remedy, but the meaning of the term Botox is a central issue in this case. If the term is generic as a matter of law, it has direct implications on the legality of Dr. Poet's alleged representations. As such, the Defense is prepared to present expert witnesses in the field of trademark law and the procedure of the U.S. PTO should the court require a factual hearing on this issue prior to dismissing the Indictment with prejudice.

3. The Term "Botox" has become Generic

As with the terms Thermos, Aspirin, Elevator and Escalator, it is respectfully submitted that, even if the Court were to find Botox non-generic at the time of the trademark application, it has since become generic in the American lexicon. Accordingly, it is respectfully submitted that, in the alternative of dismissing the Indictment for prior genericness, the Court should hold a hearing to determine whether the term "Botox" has become generic since its registration. The touchstone of the analysis, even in this case, is ***not*** what any particular consumer thought he or she was receiving, but the legality of using a term that has become generic in the popular sense:

> The crux of this controversy, however, lies not in the use of the word to these buyers, but to the general consuming public, composed of all sorts of buyers from those somewhat acquainted with pharmaceutical terms to those who knew nothing of them. The only reasonable inference from the evidence is that these did not understand by the word anything more than a kind of drug to which for one reason or another they had become habituated.

Beyer, 207 F. Supp. at 510. As such, it is respectfully submitted that, as admitted in ¶ 14 of the Indictment, Dr. Poet's patients sought, and received "Botox[] treatments" in the actual, and legal,

sense. This is consistent with, not only the prior generic use, but also the generic meaning that has attached to the word Botox since the time of Allergan, Inc.'s registration of the mark.

In this regard, a trademark case recently settled in the U.S. District Court for the District of Utah which addressed the very issues before this Court. Klein Becker, Inc. v. Allergan, Inc., Docket No. 2:03-cv-00514 (D. Ut. filed June 2, 2003). Two experts, Professors Michael Kamins and Marita Sturken, prepared and submitted expert reports in that case on behalf of Klein Becker which directly address the genericness of the term Botox. Professor Sturken's report addresses how Americans use the term "Botox" in everyday speech, and Professor Kamins' report provides an analysis of the consuming public's understanding of the term "Botox" based upon extensive surveys. Both of these reports were supplied to Allergan, Inc. as part of discovery in that case. Unfortunately, although both professors have agreed to testify as experts in the instant case, they have declined to make these reports available, or to discuss their contents, because of a confidentiality agreement in the litigation.

The defense needs these reports in order to mount an effective defense in any hearing concerning genericness and in any subsequent trial. As they were part of the record in a litigation, it is respectfully submitted that the defense is entitled to these reports under Fed. R. Crim. P. 17 (because they cannot be obtained under Rule 16 discovery and they are required pretrial to prepare Dr. Poet's Defense). As such, the Court should issue an Order allowing the Defense to subpoena Klein Becker, Inc. for the reports and the backup documentation which are necessary to prepare for trial.

Accordingly, if the Court were to refuse to dismiss the Indictment because of prior genericness, it is respectfully submitted it should permit a hearing on current genericness and

allow the Defense to subpoena Klein Becker, Inc. under Rule 17 for documents necessary for pretrial preparation and not otherwise available.

D. POINT 3: The Indictment Must be Dismissed on the Grounds of Judicial Estoppel Because the Government Took an Inconsistent Position in a Prior Proceeding and Prevailed on that Position

In the Florida case, the Government sought, and obtained, an Injunction based upon the fact that Dr. Livdahl and his company, TRI, was committing fraud against the individuals[7] to whom he was advertising his product because the product that he sold was misbranded in violation of 21 U.S.C. §§ 331(a) and 252(f). The significance of this is two-fold. The Government first alleged that individuals who were receiving promotions and advertisements and being educated were being misled into believing that the TRI product was FDA approved for human use. Hughes Cert., at ¶ 9, Exhibit 8 (FDA Complaint, at page 23). By the Government's own admission, only physicians and surgeons were being sent promotions and advertisements, and only physicians and surgeons were being educated on the TRI product. Id. Hence, when the Government prevailed on its injunctive relief application based upon its extensive evidence provided to the District Court showing that the physicians and surgeons, like Dr. Poet, were ***fraud victims***, it is now precluded from suggesting to this Court that Dr. Poet is an offender in this case based on the same evidence. It is simply disingenuous and reeks of unfairness. This is particularly so since the Government alleged in the Florida case that the ***same*** items that were shipped to Dr. Poet ***had been misbranded before they ever entered into the stream of commerce***. Id., at ¶ 42, Exhibit 41 (Government Brief, at pages 5 – 18) (detailing why the TRI product was misbranded ***prior*** to introduction into interstate commerce). The Government ***now*** alleges that Dr. Poet misbranded the TRI product ***after*** it had been shipped in interstate commerce.

[7] *i.e.*, Dr. Poet and thousands of other physicians and surgeons.

As the Third Circuit has noted, the Doctrine of Judicial Estoppel is designed to prevent litigants from playing fast and loose with the courts. Park v. United States, 2006 U.S. App. LEXIS 32048, at * 18 (3rd Cir. December 29, 2006) (quoting In re Chambers Dev. Co., 148 F.3d 214, 229 (3rd Cir. 1998)). When applied, it prevents "a litigant from asserting a position inconsistent with one that she has previously asserted in the same or in a previous proceeding." Id. It can, and has, been applied against the Government in criminal proceedings. See Beem v. McKune, 317 F.3d 1175, 1185 (10th Cir. 2003) (providing examples and cites of the doctrine's application in criminal cases because it "should be universally available. . . ."). In order for Judicial Estoppel to attach, the Supreme Court has stated that several factors are relevant:

> First, a ***party's later position must be clearly inconsistent with its earlier position***. Second, courts regularly inquire ***whether the party has succeeded in persuading a court to accept that party's earlier position***, so that judicial acceptance of an inconsistent position in a later proceeding would create the ***perception*** that either the first or the second court was misled. Absent success in a prior proceeding, a party's later inconsistent position introduces no risk of inconsistent court determinations, and thus poses little threat to judicial integrity. A third consideration is ***whether the party seeking to assert an inconsistent position would derive an unfair advantage or impose an unfair detriment on the opposing party*** if not estopped.

New Hampshire v. Maine, 532 U.S. 742, 750-751 (2001) (emphasis added).

It is respectfully submitted that the doctrine should apply to the case at bar. First, the Government took an inconsistent position in the Florida case with respect to the status of the physicians to whom TRI was marketing its product ***and*** the fact that the TRI product was misbranded prior to its introduction into interstate commerce. It then prevailed on that position. ***Now, after having convinced the Florida District Court that physicians like Dr. Poet need to be protected from Chad Livdahl's misrepresentations concerning the misbranded TRI product, it now seeks to punish Dr. Poet for falling victim to that exact conduct by misbranding an already misbranded product***. It is unfair, unjust, and will result in a clearly inconsistent legal

outcome should Dr. Poet be convicted. The prejudice and unfair detriment to him is readily apparent. Accordingly, it is respectfully submitted that the Court should dismiss the Indictment, with prejudice, in its entirety.

E. POINT 4: The Court Should Dismiss the Indictment without Prejudice Because of the FDA's and the Government's Due Process Violations with Respect to Failure to Provide an Administrative Hearing and Failure to Provide Exculpatory Materials

There are two separate grounds upon which the Court may dismiss the Indictment without prejudice. Viewed as a whole, however, they form strong basis to require the FDA and the Government to comply with federal law by seeking an indictment anew.

1. The Indictment Must be Dismissed without Prejudice for Failure to Provide Dr. Poet with an Administrative Hearing Required Under the Food, Drug and Cosmetic Act.

As explained supra, Congress retained the administrative hearing requirement prior to reporting violations to the U.S. Attorney in the 1938 Act. 21 U.S.C. § 335. Under this provision, "[b]efore any violation of this chapter is reported by the Secretary to any United States attorney for institution of a criminal proceeding, the person against whom such proceeding is contemplated ***shall*** be given appropriate notice and an opportunity to present his views, either orally or in writing, with regard to such contemplated proceeding." Id. (emphasis added). This is not a Congressional recommendation, nor is it a discretionary proceeding. Congress used the term "***shall***," and that confers a right. Indeed, Congress expounded on what it intended under § 335 in 1968 by including a definition of "informal hearing" in 21 U.S.C. § 321(x). This section is quite precise, in that it requires a presiding officer and a level of procedure to be followed. Id.

The Commissioner of the U.S. Department of Health and Human Services then promulgated regulations in 1979 regarding when the notice is to be given, how the notice is to be

served, and the procedure employed before, during and after the informal hearing. 21 C.F.R. §§ 7.84 – 7.87. Like the statute, the regulations confer a right by speaking in mandatory terms:

> A person against whom criminal prosecution under the Federal Food, Drug, and Cosmetic Act is contemplated by the Commissioner of Food and Drugs ***shall be given appropriate notice and an opportunity*** to present information and views to show cause why criminal prosecution should not be recommended to a United States attorney.

21 C.F.R. § 7.84(a)(1) (emphasis added). Unlike the statute, however, the regulations conferred some level of discretion upon the Secretary to refuse to provide such an informal hearing. 21 C.F.R. § 7.84(a)(2) and (3). One exception relates to the fear of destruction of evidence and risk of flight, and the other exception applies if the commissioner "contemplates further investigation ***by*** the Department of Justice." Id. (emphasis added). Neither of these exceptions apply because there is no evidence, on the record or otherwise, that Dr. Poet eliminated evidence or posed a risk of flight. Further, as S/A Hess' Memoranda of Interviews show, it was always the FDA, and not the Department of Justice, conducting this investigation. Finally, the regulations require that any informal hearing include any additional charges relating to the conduct, even if no hearing is required under the Food, Drug and Cosmetic Act:

> If an apparent violation of the Federal Food, Drug, and Cosmetic Act also constitutes a violation of any other Federal statute(s), and the Commissioner contemplates recommending prosecution under such other statute(s) as well, the notice of opportunity to present views ***will include all violations***.

21 C.F.R. § 784(c) (emphasis added).

Quite simply, Congress conferred a right to a hearing. The FDA never gave Dr. Poet the opportunity to express his views prior to its recommendation to indict him, and he is entitled to such a hearing.

It must be noted that the Supreme Court held in a 1943 case that the informal hearing "is not a prerequisite to prosecution." Dotterweich, 320 U.S. at 279. This holding, which comprises two sentences of a fifteen page opinion, merely upheld a 1911 Court decision finding that the

failure to provide an informal hearing under section 4 of the 1906 Act was not a jurisdictional issue. United States v. Morgan, 222 U.S. 274, 280 (1911). These cases are distinguishable from the case at bar because of the facts and because of the relief sought.[8]

First, and foremost, the defendants in both Dotterweich and Morgan were convicted of misbranding after a trial, and they sought to overturn their convictions based upon the failure of FDA to provide them with an informal hearing. Such is not the case here, as Dr. Poet seeks to avail himself of the right to his hearing prior to any finding of guilt. It is respectfully submitted that an un-convicted defendant stands in very different shoes than a defendant who has stood trial and been found guilty.

Second, and most important, the Defense ***does not*** seek to bar prosecution or to make his arguments on jurisdictional grounds. Rather, the FDA's failure in an investigation and prosecution ***it initiated*** constitutes an abrogation of Dr. Poet's right to due process, thus allowing the Court great leeway to fashion relief. Since the time Dotterweich, the state of due process law has evolved such that the Court now ***requires*** district courts to enforce rights conferred by statute and, sometimes, by regulation. In United States v. Caceres, 440 U.S. 741 (1979), the Court reversed a suppression order relating to undercover tape recordings of the defendant that were made in violation of the internal policies of the IRS. In so holding, the Court noted that the undercover recordings did not violate the Constitution or any statute, and that the IRS "was not required by the Constitution or by statute to adopt any particular procedures or rules before engaging in consensual monitoring and recording." Id. at 749.

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[8] Certainly there are cases citing Dotterwich and Morgan as justification for refusal to grant relief. See, e.g., Kent v. Benson, 945 F.2d 372 (11th Cir. 1991); United States v . Prigmore, 243 F.3d 1 (1st Cir. 2001). In these cases, however, the issue before the Court was whether the statute is jurisdictional, which the Defense does not dispute here. Rather, the Defense's argument sounds in due process based upon ***administrative failure to provide a statutorily mandated hearing in an investigation initiated by the FDA***. This issue, we submit, has never been raised.

The Court, however, contrasted the absence of a statutory duty in Caceres with the presence of such a duty in Bridges v. Wixon, 326 U.S. 135, 152-53 (1945), where the INS violated a regulation specifically designed to provide deportable aliens due process. Id. In so holding, the Court cautioned district courts as to when their duty is required:

> A court's ***duty to enforce*** an agency regulation is most evident when compliance with that regulation is ***mandated*** by the Constitution ***or federal law***.

Id. (emphasis added). Known as the "Caceres Doctrine," this was merely a reiteration of long-standing Supreme Court precedent requiring executive agencies to follow their own rules and the laws passed by Congress. As stated in Morgan v. Ruiz, 415 U.S. 199, 235 (1974):

> Where rights of individuals are affected, it is incumbent upon agencies to follow their own procedures. This is so even where the internal procedures are possibly more rigorous that otherwise would be required.

Id. The Third Circuit, in applying the Caceres Doctrine, has held that "the Due Process Clause is implicated only when an agency violates regulations ***mandated*** by the Constitution or ***by law***. . . ." Tolchin v. The Supreme Court of the State of New Jersey, 111 F.3d 1099, 1115 (3rd Cir. 1997) (emphasis added).

It is respectfully submitted that Congress intended to insert additional safeguards into prosecutions – like this one – initiated by the FDA because the issue of whether a drug is misbranded is so technical, Congress intended to leave the decision of whether criminal prosecution was warranted with those in the FDA who are best able to make that determination. See Johnson, 221 U.S. at 498. This argument does not suggest that the U.S. Attorney Office does not have the right, on its own, to initiate investigations. Long-standing jurisprudence holds that it does. Where, however, the FDA initiates the investigation, conducts the investigation, and then recommends to the U.S. Attorney that the issue be presented to the grand jury, ***it is***

respectfully urged that the FDA must follow the plain language of the law which requires a hearing before the recommendation.

Here, the FDA failed to provide the opportunity for a hearing. Given the other infirmities in the FDA's investigation and provision of discovery, it is respectfully submitted that a dismissal *without prejudice* is the least drastic remedy that preserves the ability of the U.S. Attorney's Office to proceed with prosecution while ensuring that the FDA discharges its statutorily-mandated duty. ***To hold otherwise would risk conveying the impression to litigants thrown out of court for failing to abide by agency regulations or statutory procedure that the laws enacted by Congress really do not apply to the executive agencies charged with enforcing them.***

2. The FDA has Violated Dr. Poet's Right to Due Process and *Brady* by Intimidating Witnesses and Failing to Provide Exculpatory Information

a. Intimidation of Witnesses

It is without question that before the investigation of Dr. Poet ever began, the FDA knew the symptoms of botulism and the time-frame (6 hours to 10 days) within which they occur. Hughes Cert., at ¶¶ 10 and 12, Exhibits 9 (CDC Manual) and 11 (FDA Medical Review). Indeed, the FDA has noted that once cranial (head) nerves are involved, there is an onset of symptomatic descending paralysis that can only be halted through the administration of equine antitoxin. Id. at ¶ 12, Exhibit 11 (FDA Medical Review, at 11). Hence, it is outrageous that the FDA waited until after Dr. Poet rejected the U.S. Attorney's plea offer – nearly 20 months after any of TRI's product was possessed by Dr. Poet – to contact many of Dr. Poet's patients to discuss their "exposure" to an unapproved form of Botulinum Toxin Type A. Id. at ¶ 49, Exhibit 48. As stated previously, the identities of these patients were well-known to the FDA over a year

prior to the letter. To increase the patient's level of fear, each received a subsequent letter informing them that they might be a "victim" of Dr. Poet's fraud. Id. at ¶ 50, Exhibit 49.

The right of the FDA to interview witnesses in preparation for prosecution is not questioned. However, the ***method*** by which they sought to encourage their assistance – by frightening them into believing that they had been sickened as a result of a fraud – demonstrates the FDA investigator's intent to taint potential defense witnesses by unfairly playing upon their fears. No where is this more evident than S/A Hess' false statements to witnesses indicating that the same product used by Dr. Poet caused four people in Florida to become paralyzed. O'Brian Cert. at ¶ 4; Blankenbuehler Cert., at ¶ 4; Buterick Cert., at ¶ 4; Spagnola Cert., at ¶ 3.[9] As stated previously, the FDA and the Government knew, as early as December 23, 2004, that TRI's product was not involved in the four Florida botulism cases. Id., at ¶ 42, Exhibit 41 (Government Brief, at page 7, n.6).

At least two witnesses have been adversely impacted by S/A Hess' improper tactics. Patient Joan Hall, based on information she obtained from S/A Hess, believes that she contracted botulism from Dr. Poet, and she has refused to submit to any interview with the Defense. Id. at ¶ 54, Exhibit 53 (notes of Joan Hall conversation). Further, S/A Hess impacted her testimony so greatly that she now wishes "ill luck" upon Dr. Poet. Id. at ¶ 55, Exhibit 54. Additionally, patient Theresa McCormick was so frightened by S/A Hess' tactics that she refused to sign a certification confirming her account of her interview with S/A Hess and indicated that she did not desire to testify. Blankenbuehler Cert., at ¶ 6. To date, numerous patients have failed to return the Defense's calls requesting an interview, indicating that S/A Hess' conduct may have a broader impact than just a few patients.

[9] It is also quite troublesome that FDA S/A Hess' interview reports fail to detail his statements to the witnesses and that the content of the reports appear to differ substantially from the witnesses' accounts of the interviews.

It is long-standing law that a Government agent's "intimidation that dissuades a potential defense witness from testifying for the defense can, under certain circumstances, violate a defendant's right to present a defense." United States v. Williams, 205 F.3d 23, 29 (2nd Cir. 2000); Webb v. Texas, 409 U.S. 95, 97-98 (holding that intimidation of witness "drove that witness off the stand, and thus deprived the petitioner of due process of law under the Fourteenth Amendment."); United States v. Golding, 168 F.3d 700 (4th Cir. 1999); United States v. Vavages, 151 F.3d 1185, 1190-92 (9th Cir. 1998); United States v. Heller, 830 F.2d 150, 153-54 (11th Cir. 1987); United States v. Morrison, 535 F.2d 223 (3rd Cir. 1976) (dismissing conviction because of government witness intimidation); Government of the VI v. Smith, 615 F.2d 964 (3rd Cir. 1980). As such, FDA S/A Hess' conduct of lying and intimidating witnesses to affect their testimony was "a misuse of investigative techniques legitimately directed at exploring whether witness testimony is truthful and complete and whether the government has acquired all incriminating evidence." Moore v. Valder, 65 F.3d 189, 194 (D.C. Cir. 1996). Moreover, in the Third Circuit, the "good faith" of the Government agent in engaging in intimidating conduct is irrelevant to the issue whether the agent's conduct resulted in a due process violation to the defendant. Morrison, 535 F.2d at 227.

Accordingly, it is respectfully submitted that the conduct here violates the concepts of "fundamental fairness, shocking to the universal sense of justice." United States v. Russell, 411 U.S. 423, 431-32 (1973). Alone, it appears to have tainted Dr. Poet's ability to muster witnesses to aid in his defense, thus rendering any trial suspect. The FDA agent's further action of withholding exculpatory materials from the defense while burying the defense in discovery, however, only serves to magnify the impact and the intent of that wrongful conduct.

b. The Brady Violations

As the Hughes Certification demonstrates, the Government unquestionably failed to provide the Defense with exculpatory information. Hughes Cert., at ¶¶ 7, 11, 39, 40-43, 49-53, 55-57, 68-73. As the Court is aware, a prosecutor is forbidden from suppressing "evidence favorable to an accused upon request . . . where the evidence is material either to guilt or punishment, ***irrespective of the good faith or the bad faith of the prosecutor***." Brady v. Maryland, 373 U.S. 83, 87 (1963) (emphasis added). In order to establish a due process violation, "a defendant must show that: (1) evidence was suppressed; (2) the suppressed evidence was favorable to the defense; and (3) the suppressed evidence was material to either guilt or punishment." United States v. Pelullo, 399 F.3d 197, 209 (3rd. Cir. 2005) (quoting United States v. Dixon, 132 F.3d 192, 199 (5th Cir. 1997)).

In the instant case, Dr. Poet has a defense that he purchased TRI's BoNT/A in "good faith" of the representations made by Dr. Chad Livdahl and his employees. United States v. Gross, 961 F.2d 1097, 1103 (3rd Cir. 1992) (noting that a defendant's "good faith" conduct is inconsistent with knowing and willful conduct).[10] The Government had the transcript of the grand jury testimony of a former TRI employee in which she detailed how Chad Livdahl attempted to deceive physicians inquiring about and purchasing his BoNT/A. Hughes Cert., at ¶ 39, Exhibit 38. Further, it had a transcript of a tape-recorded conversation (and the tape itself) in which Livdahl subsequently attempted to discuss this employee's testimony. Id. at ¶ 68, Exhibit 67. These items tend to show Dr. Chad Livdahl's intent to defraud the physicians into purchasing TRI's BoNT/A, which includes Dr. Poet. ***These materials, along with numerous***

[10] The FDA and the Government are well aware of this because numerous other physicians told the FDA about Dr. Chad Livdahl's misrepresentations to them to entice them to purchase TRI's BoNT/A along with his explanations about the warnings. Hughes Cert., ¶¶ 2-6, Exhibits 1-5. Exhibits 1-4 ***were*** included in the Government's third round of discovery, Exhibit 5 was not.

other exculpatory items, were provided to another physician charged with the same offenses as Dr. Poet because they contained exculpatory information, but they were not provided here.

Moreover, FDA S/A Hess' Memorandums of Interview clearly contain exculpatory information in that patients indicated that they did not feel defrauded, that they saw no problem with utilizing a non-FDA approved BoNT/A, and that they had good results from their treatments with Dr. Poet. Hughes Cert., at ¶¶ 50-53 and 69-73, Exhibits 49-52 and 68 – 72. Given the fact that the Government concedes that many patients received Allergan, Inc.'s BOTOX® from Dr. Poet, Indictment, at ¶ 13, it is certainly exculpatory evidence if a patient was satisfied by the treatment that he or she sought from Dr. Poet.[11] Further, as the Certifications of employees Toth and Gifford indicate, both testified in the grand jury consistent with their prior interviews with the Government. Given the fact that these interviews themselves contain exculpatory information, the Government's failure to provide these transcripts is yet another violation.

Perhaps what is most troubling is the fact that the Government first insisted that there was no additional exculpatory evidence, and then, through FDA S/A Hess, provided several thousands of pages of information containing some exculpatory but mostly irrelevant information. Id. at ¶¶ 58 – 67, Exhibits 57 -66. ***This conduct is compounded in light of the fact that approximately 37 of FDA S/A Hess' interview reports were produced in another prosecution as exculpatory evidence, but not in this case***. This circumstance is no different than those in Banks v. Dretke, 540 U.S. 668, 692 (2004) and Strickler v. Greene, 527 U.S. 263, 276, 282 (1999), where the Supreme Court found due process violations when the prosecutions in each of these cases represented to the defense that they had provided all exculpatory materials,

[11] In this regard, Paragraph 13 of the Indictment simply does not make sense. In essence, the Government is alleging that it was part of Dr. Poet's "scheme and artifice to defraud" to ***not*** defraud patients by giving them Allergan, Inc.'s product.

knowing that the files made available to the defense did not contain highly relevant impeachment information.

There are only two possibilities: either all of FDA S/A Hess' interview reports are exculpatory evidence and hence required to be produced in the instant case, or the Government has engaged in willful discovery misconduct by producing thousands of pages of irrelevant documents, containing intermittent exculpatory materials, in an effort to hamper the defense's ability to prepare its defense.[12] The Government cannot have it both ways.

c. Impact Upon this Case

It is respectfully submitted that the Government agent's conduct in this case, given the totality of the circumstances, is so pervasive and outrageous that it violates all fundamental concepts of fair play and the impartial administration of justice warranting a dismissal with prejudice. See United States v. Twigg, 588 F.2d 373 (3rd Cir. 1978). This is the Defense's primary request. It is conceded, however, that the Third Circuit has cautioned district courts to proceed with extreme restraint in this regard. United States v. Voight, 89 F.3d 1050, 1064-66 (3rd Cir. 1996). Accordingly, it is respectfully submitted that, given the FDA's violation of Dr. Poet's due process rights by: 1) failing to provide an administrative hearing when required to do so by law; 2) engaging in the intimidation of witnesses designed to deny the defense their testimony; and 3) engaging in clear discovery abuses resulting in Brady violations, the Court

[12] In this regard, we are mindful of, and appreciate, the Prosecution's desire to avoid Brady violations by producing more information than might otherwise be required. But here, where so many clearly irrelevant documents were produced while so many clearly exculpatory documents were withheld, the FDA agent's efforts in gathering and producing the Government's discovery must necessarily give the Court pause. In this regard, the Government, and its agents, should be held to no less stringent a standard as any other litigant engaged in civil litigation before this Court. Tarlton v. Cumberland Co. Correctional Facility, 192 F.R.D. 165 (D. NJ. 2000) (Judge Kugler imposing sanctions for failure to provide relevant discovery); see 18 U.S.C. 3006A, Pub. L. 105-119, Title VI, § 617 (Nov. 26, 1997) (Hyde Amendment allowing award of attorney's fees to criminal defendants where Government position found to be "vexations, frivolous or in bad faith".).

would be well within its discretion to require the Government to start anew by dismissing the Indictment without prejudice.

F. POINT 5: The Defense is Entitled to an Order Directing the FDA to Review all of the Evidence in all Related FDA Cases Nationwide Involving TRI's BoNT/A and to Produce All Exculpatory Documents, including Grand Jury Transcripts and Witness Interviews in the Instant Case

If the Court is disinclined to dismiss the Indictment based upon the FDA's conduct, the Defense is nonetheless entitled to exculpatory information that the Government has heretofore refused to produce. While the Defense has obtained *some* of this information through other means, it does not relieve the Government of its responsibility to diligently search for exculpatory information and to provide it to the defense. Given the fact that the defense has already clearly demonstrated that the Government has exculpatory information that it previously claimed not to have, it is respectfully submitted that the Court must order the Government to conduct a search of all related TRI prosecutions and provide exculpatory materials to the defense.

This information must necessarily include any Grand Jury testimony, in the instant case and in others, which tends to corroborate Dr. Poet's "good faith," Dr. Chad Livdahl's deceptive practices, and any patient's satisfaction with the results from their treatment with Dr. Poet. Additionally, it is respectfully submitted that as FDA S/A Hess' Memorandum's of Interview have already been deemed exculpatory by at least one other Justice Department Prosecutor, ***all*** of Memorandums of Interview should be produced. This is especially important as it is apparent that many patients indicated to the FDA that they had "no adverse affects" or were pleased with their treatment with Dr. Poet. Accordingly, these interviews – especially those where the patient reported "no adverse affects" – tend to show that the patient was ***not*** defrauded.

G. POINT 6: The Defense is Entitled to the Grand Jury Transcripts, or in the Alternative, to an In-Camera Review to Determine whether the Government Met its Obligations

As suggested by the Certifications of Laurie Toth and Heather Gifford, at least some of the Grand Jury Transcripts contain exculpatory information to which the defense is entitled. Moreover, the Defense has made a prima facie showing of misconduct such that it warrants, at the very least, an *in-camera* review of the Grand Jury Transcripts in this case to determine whether FDA S/A Hess made any misrepresentations to the Grand Jury concerning the four botulism cases in Florida. Furthermore, as the Defense has shown, the Government was well aware of Dr. Chad Livdahl's deceptive conduct through its documentary evidence and its interviews with other physicians, ***long before any presentment was made to a Grand Jury in this case***. This conduct is exculpatory evidence, and under N.J. R. Prof. C. 3.8(d), the prosecution is required to present exculpatory evidence to the grand jury. Under the "McDade Amendment," 28 U.S.C. § 530B, the Government is required to abide by the New Jersey Supreme Court's Rules of Professional Conduct.

It is respectfully submitted that the Defense has satisfied its burden and particularlized need under Fed. R. Crim. P. 6(e)(2)(E)(ii). Accordingly, we request that the Court order the Government to produce these transcripts, or in the alternative, to review these transcripts, *in camera*, to determine whether the Government's obligations have been satisfied.

H. POINT 7: The Defense is Entitled to Supression of any Patient-Witness Testifying For the Government and Inteviewed by S/A Hess, or in the Alternative, Additional Deposition and Document Discovery Under Fed. R. Crim. P. 15 and 17

It is respectfully submitted that any patient-witness testifying for the Government who had been interviewed by FDA S/A Hess has necessarily been tainted and should therefore be barred from testifying. This is especially so since apparently FDA S/A Hess' conduct has

prejudiced at least two witnesses to such a degree that one believes that Dr. Poet infected her with botulism and the other refuses to testify for the defense. Suppressing this evidence, in lieu of dismissing the indictment, might be a proper remedy.

In the alternative, however, it is respectfully submitted that, in addition to the Memoranda of Interview, the Government should provide a list of all patients to whom the FDA sent its "you might have been exposed" letter. In addition, as at least one patient now claims to have suffered disease as a result of her treatment with Dr. Poet, the Defense is entitled under Fed. R. Crim. P. 15 and 17 to depose any witness claiming injury and to require that witness – and their physician – to provide documents, pretrial, concerning their condition. The rationale behind this request is straightforward: ***if the Government is going to allege at trial that any patient was harmed from Dr. Poet's use of the TRI BoNT/A, then Dr. Poet must be given the opportunity to examine that patient's medical complaints before trial, and if necessary, present expert witness testimony to negate causation.*** No patient who believes that Dr. Poet has caused harm will voluntarily submit to a defense interview, particularly if their feelings have been influenced in a manner consistent with others interviewed by FDA S/A Hess. This information simply cannot be obtained prior to trial, and it is necessary for Dr. Poet to formulate any defense. To hold otherwise will necessarily result in an unfair surprise at trial and Dr. Poet's corresponding inability to refute any claims.

I. POINT 8: The Court Should Allow the Defense to Issue Subpoenas Under Fed. R. Crim. P. 17 for Certain Documents and Other Materials

As outlined above, the Defense has knowledge that at least one third party has information directly impacting on the issues in this case. Because our intended experts require this material, which the Defense must produce to the Government pretrial, we respectfully request that the Court permit the Defense to issue a Rule 17 subpoena to Klein Becker, Inc. for

the expert reports, and backup documentation, of Professors Kamin and Sturken. None of these materials can be obtained under Rule 16, and the Defense has demonstrated its need for these items pretrial.

In addition, the FDA's interview reports have revealed that List Laboratories, Inc. possesses certain information relating to the BoNT/A it sold to Dr. Chad Livdahl, who in turn sold it to Dr. Poet. Hughes Cert., at ¶¶ 37 and 38, Exhibits 36 and 37. As there appears to be an extreme variance in the FDA's analyses of various samples of the TRI BoNT/A, the Defense requires certain documentation from List Laboratories, Inc. to determine whether the Defense will object to the Government's use of its scientific evidence. None of these items have been produced to the Defense by the Government under Rule 16 (indeed, we do not even know if the Government has them). Having demonstrated a need for this evidence pretrial, it is respectfully submitted that the Court should permit a Rule 17 subpoena to issue to List Laboratories, Inc.

Finally, it is respectfully submitted that Allergan, Inc. has information relating to its efforts to produce a new BoNT/A product nearly identical to that of TRI. Additionally, the interview reports produced by the Government appear to suggest that there has been extensive contact between representatives of the Government and Allergan, Inc. pertaining to the various TRI prosecutions. In order to permit Dr. Poet to prepare his Defense, pretrial, it is respectfully submitted that the Court permit Dr. Poet to issue a Rule 17 subpoena to Allergan, Inc. for information that is necessary and cannot be obtained under Rule 16.

J. POINT 9: The Court Should Permit Certain Depositions Under Fed. R. Crim. P. 15

The Defense's investigation has revealed that there are certain witnesses, who may have exculpatory information, who are located in the western portion of the United States and have refused, or may refuse, to testify because of the hardship that travel will place upon them. These

witnesses include former TRI employees as well as several physicians, whose patients' demands require that they not travel far from their practice. This circumstance is complicated by the fact that their testimony may be required in more than one criminal trial concerning Dr. Chad Livdahl's sale of TRI's BoNT/A to physicians.

Accordingly, it is respectfully requested that, in the interest of judicial efficiency and the fair administration of justice, the Court consider coordinating Rule 17 subpoenas of these witnesses with other district courts where cases identical to the instant case are pending. In such a manner, the Defense will not be denied its witnesses, and the Government will suffer no prejudice.

K. POINT 10: The Defendant is Entitled to a Bill of Particulars

The Indictment does not specify whether any particular patient was a victim of Dr. Poet's conduct, and as already stated, the FDA's interview reports indicate that the vast majority of Dr. Poet's patients were satisfied with the treatments that they received from Dr. Poet. Given the fact that the Government concedes that at least ***some*** patients were ***not*** defrauded because they received Allergan, Inc.'s BOTOX®, it is respectfully submitted that the defense is entitled to at least some indication as to which of Dr. Poet's patients the Government believes were defrauded by having received TRI's BoNT/A particularly since not all patients received the FDA's and the US Attorney letters. In addition, it is necessary to know which of Dr. Poet's patient's believe they were victims, particularly after having received notifications from both the FDA and the U.S. Attorney's Office informing them that they were victims. As such, it is respectfully submitted that the Defense is entitled to know which of Dr. Poet's patients responded to the Government's and the FDA's inquiries.

L. POINT 11: The Indictment Should be Amended to Refer to Allergan, Inc.'s Accurate Claimed Mark: BOTOX® Cosmetic

The Indictment inconsistently refers to Allergan, Inc.'s product as Botox® and Botox® Cosmetic interchangeably. This is simply wrong. BOTOX® is Allergan, Inc.'s trademark registered with the U.S. PTO. Hughes Cert., at ¶¶ 34 and 35, Exhibits 33 and 34. This is also the assigned name of the drug approved by the FDA for the treatment of certain eye and cranial dystonias. BOTOX® COSMETIC is the name of the drug approved by the FDA for the treatment of certain forehead wrinkles. Id. at ¶ 32, Exhibit 31. Although BOTOX® is, in every chemical and biological sense, identical to BOTOX® COSMETIC, the FDA has mandated that Allergan, Inc. label its product differently according to its intended use. Hence, in accordance with Fed. R. Crim. P. 7(e), paragraphs 2(e) and (f), 13, 14, and 18 through 20 of Counts One through Thirteen, and paragraph 2 of Count Fourteen must be amended as follows:

Counts One through Thirteen

2(d): Botox® - change to BOTOX®
2(e): Botox® - change to BOTOX®
Botox® Cosmetic – change to BOTOX® COSMETIC
13: Botox® Cosmetic – change to BOTOX® COSMETIC
14: Botox® - change to BOTOX® COSMETIC
18: Botox® - change to BOTOX® COSMETIC
19: Botox® - change to BOTOX® COSMETIC
20: Botox® - change to BOTOX® COSMETIC

Count Fourteen

2: Botox® and Botox® Cosmetic – change to BOTOX® COSMETIC

These amendments will reflect the accurate and permitted use of Allergan, Inc.'s BoNT/A as mandated by the FDA. Any other use would be improper.

M. POINT 12: The Court Should Designate this Case as a Complex Case Under the Speedy Trial Act to Permit the Parties to Engage in Additional Discovery and Investigation

As set forth above, both the Government and the Defense have significant additional work to accomplish in order to properly prepare for trial I the instant case. The Government's production of additional discovery will necessarily require additional investigation by the Defense, and the Defense's experts, when retained, will require time to review the materials that it is hoped the Court will order produced. Accordingly, the Defense respectfully requests that this Court should designate this case as a "complex case" under 18 U.S.C. § 3161(h)(8)(A) and (B)(ii) and exclude additional time under the Speedy Trial Act.

CONCLUSION

For the reasons set forth above, it is respectfully submitted that the Court grant Dr. Albert Poet the relief he seeks, principally, dismissal of the Indictment, or in the alternative, the interim pretrial remedies that will ensure a fair and just trial.

Respectfully submitted,
COOPER LEVENSON APRIL
NIEDELMAN & WAGENHEIM, P.A.

Dated: 1/16/07

By: /s William J. Hughes, Jr. (WH-1924)
William J. Hughes, Jr.
Counsel to Dr. Albert Poet

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